US3832237 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: KC Joubran

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US3832237
Form: Participant Creation
Data signed: (b) (4) **21 Feb 2021 21:38:37**
Generated On: 10 Jun 2021 10:01:21

Participant ID	US3832237

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-3442937

US3832237
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3442938

US3832237
Folder: Screening
Form: Demographics
Data signed: (b) (4) **15 Feb 2021 14:27:12**
Generated On: 10 Jun 2021 10:01:21

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
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-2022-1614-3442939

US3832237
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **15 Feb 2021 14:27:12**
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3442940

US3832237
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **15 Feb 2021 14:27:12**
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3442941

US3832237
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **15 Feb 2021 14:27:12**
Generated On: 10 Jun 2021 10:01:21

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-3442942

US3832237
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **15 Feb 2021 14:27:12**
Generated On: 10 Jun 2021 10:01:21

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Start Year (derived)	1978
Stop Month and Year (derived)	
Stop Year (derived)	

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US3832237
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **15 Feb 2021 14:27:12**
Generated On: 10 Jun 2021 10:01:21

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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US3832237
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **15 Feb 2021 14:27:12**
Generated On: 10 Jun 2021 10:01:21

Condition	INSOMNIA
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)	

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US3832237
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **15 Feb 2021 14:27:12**
Generated On: 10 Jun 2021 10:01:21

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☑ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3442946

US3832237
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **15 Feb 2021 14:27:12**
Generated On: 10 Jun 2021 10:01:21

Condition	ACID REFLUX WITH NAUSEA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3442947

US3832237
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	11:12 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:12
Height *(xxx.x)*	173.4 cm
Weight *(xxx.x)*	89.4 kg
BMI *(xxx.x)*	29.73304 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	67 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	173 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	99 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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US3832237
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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.

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US3832237
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	PLANS ON ROUTINELY (E.G., WEEKLY) GOING TO PLACES WHERE PEOPLE GATHER (E.G., PLACES OF WORSHIP, RESTAURANTS, BARS, SPORTING EVENTS) OVER THE COMING MONTHS

US3832237
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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

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US3832237
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

What was the date of randomization? *(dd MMM yyyy)*	20 AUG 2020
What was the participant's randomization number?	106302
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ■ >=18 and <65 years and at risk ☐ >=65 years ☐

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

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

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US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

Height	ND - Not Done
Weight	ND - Not Done

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US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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)*	11:12 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:12
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	67 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	173 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	99 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3442955

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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)*	12:25 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:25
Temperature *(xxx.x)*	98.0 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)*	164 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	105 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3442956

US3832237
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3442957

US3832237
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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)*	11:55 (24 HR)
Treatment Date and Time (derived)	20 AUG 2020 11:55
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-2022-1614-3442958

US3832237
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	20 AUG 2020
Collection time *(00:00-23:59)*	11:33 (24 HR)
Collection date and time (derived)	20 AUG 2020 11:33

FDA-CBER-2022-1614-3442959

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	11:27	20 AUG 2020 11:27
Nasopharyngeal Swab 2	No		

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US3832237
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3442961

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 AUG 2020 12:27
PC Open Date & Time	20 AUG 2020 12:15
PC Close Date & Time	20 AUG 2020 14:45

FDA-CBER-2022-1614-3442962

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 AUG 2020 18:06
PC Open Date & Time	20 AUG 2020 15:40
PC Close Date & Time	21 AUG 2020 11:59

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US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21

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**	96.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 AUG 2020 18:27
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

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US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21

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	22 AUG 2020 18:06
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.1 °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	23 AUG 2020 17:55
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.5 °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	24 AUG 2020 23:28
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.3 °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	25 AUG 2020 18:13
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	26 AUG 2020 17:08
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-3442969

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 12:28
PC Open Date & Time	20 AUG 2020 12:15
PC Close Date & Time	20 AUG 2020 14:45

FDA-CBER-2022-1614-3442970

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21

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	20 AUG 2020 18:06
PC Open Date & Time	20 AUG 2020 15:40
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-3442971

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21

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	21 AUG 2020 18:27
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21

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	22 AUG 2020 18:06
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21

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	23 AUG 2020 17:53
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-3442974

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21

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	24 AUG 2020 23:29
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-3442975

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21

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 18:11
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21

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	26 AUG 2020 17:04
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

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

FDA-CBER-2022-1614-3442978

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	20 AUG 2020 12:28
PC Open Date & Time	20 AUG 2020 12:15
PC Close Date & Time	20 AUG 2020 14:45

FDA-CBER-2022-1614-3442979

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-2022-1614-3442980

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	20 AUG 2020 18:07
PC Open Date & Time	20 AUG 2020 15:40
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-3442981

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3442982

	Yes ☐
PC Time stamp	21 AUG 2020 18:28
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3442984

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21

	Yes ☐
PC Time stamp	22 AUG 2020 18:06
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3442986

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21

	Yes ☐
PC Time stamp	23 AUG 2020 17:53
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-3442987

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3442988

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21

	Yes ☐
PC Time stamp	24 AUG 2020 23:29
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-3442989

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3442990

	Yes ☐
PC Time stamp	25 AUG 2020 18:11
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3442992

	Yes ☐
PC Time stamp	26 AUG 2020 17:05
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3832237
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 14:27:11**
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3442994

US3832237
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 14:27:11**
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3442995

US3832237
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	3 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-2022-1614-3442996

US3832237
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3442997

US3832237
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3442998

US3832237
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3442999

US3832237
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3443000

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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)*	10:14 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:14
Temperature *(xxx.x)*	97.7 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)*	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	98 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3443001

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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)*	11:00 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:00
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	92 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3443002

US3832237
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3443003

US3832237
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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)*	10:30 (24 HR)
Treatment Date and Time (derived)	17 SEP 2020 10:30
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-2022-1614-3443004

US3832237
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	17 SEP 2020
Collection time *(00:00-23:59)*	10:28 (24 HR)
Collection date and time (derived)	17 SEP 2020 10:28

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	10:23	17 SEP 2020 10:23
Nasopharyngeal Swab 2	No		

US3832237
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3443007

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °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	17 SEP 2020 11:01
PC Open Date & Time	17 SEP 2020 10:50
PC Close Date & Time	17 SEP 2020 13:20

FDA-CBER-2022-1614-3443008

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21

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**	95.9 °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	18 SEP 2020 05:56
PC Open Date & Time	17 SEP 2020 14:15
PC Close Date & Time	18 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 SEP 2020 21:28
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °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	20 SEP 2020 01:16
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.8 °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	20 SEP 2020 22:15
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21

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**	95.9 °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	21 SEP 2020 16:51
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.3 °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 20:44
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21

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**	95.6 °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	24 SEP 2020 02:33
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21

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 11:02
PC Open Date & Time	17 SEP 2020 10:50
PC Close Date & Time	17 SEP 2020 13:20

FDA-CBER-2022-1614-3443016

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21

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 05:56
PC Open Date & Time	17 SEP 2020 14:15
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-3443017

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21

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	18 SEP 2020 21:28
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21

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	20 SEP 2020 01:13
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21

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 22:15
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21

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 16:52
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21

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 20:45
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21

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	24 SEP 2020 02:32
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

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

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	17 SEP 2020 11:02
PC Open Date & Time	17 SEP 2020 10:50
PC Close Date & Time	17 SEP 2020 13:20

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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 ☐

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 SEP 2020 05:56
PC Open Date & Time	17 SEP 2020 14:15
PC Close Date & Time	18 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3443028

	Yes ☐
PC Time stamp	18 SEP 2020 21:28
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3443030

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21

	Yes ☐
PC Time stamp	20 SEP 2020 01:13
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-3443031

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3443032

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21

	Yes ☐
PC Time stamp	20 SEP 2020 22:15
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3443034

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21

	Yes ☐
PC Time stamp	21 SEP 2020 16:51
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-3443035

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3443036

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21

	Yes ☐
PC Time stamp	22 SEP 2020 20:45
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3443038

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21

	Yes ☐
PC Time stamp	24 SEP 2020 02:32
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3832237
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3443040

US3832237
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3443041

US3832237
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 14:27:11**
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3443042

US3832237
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 14:27:11**
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3443043

US3832237
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 14:27:11**
Generated On: 10 Jun 2021 10:01:21

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	08 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-2022-1614-3443044

US3832237
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 14:27:11**
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3443045

US3832237
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-3443046

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	15 OCT 2020
Time of assessment *(00:00-23:59)*	10:25 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 10:25
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	74 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3832237
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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

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

US3832237
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	15 OCT 2020
Collection time *(00:00-23:59)*	10:35 (24 HR)
Collection date and time (derived)	15 OCT 2020 10:35

US3832237
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 14:27:21**
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3443050

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 OCT 2020 08:29:12
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

FDA-CBER-2022-1614-3443051

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21

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 08:47:05
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21

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	05 NOV 2020 22:10:05
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 ☐

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

US3832237
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 10 Jun 2021 10:01:21

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

US3832237
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

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-2022-1614-3443057

US3832237
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3443058

US3832237
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 10:01:21

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 ☐

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Generate Next COVID-19 Assessment	Yes ☐ No ☐

US3832237
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21

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

FDA-CBER-2022-1614-3443061

US3832237
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 10:01:21

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

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

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

US3832237
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **21 Feb 2021 21:38:37**
Generated On: 10 Jun 2021 10:01:21

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

If Yes, enter details on the Adverse Events form.

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US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **21 Feb 2021 21:38:37**
Generated On: 10 Jun 2021 10:01:21

AEID	
Adverse event	WORSENING OF HYPERTENSION
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)*	15 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)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ■ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	INCREASE IN LOSARTAN MEDICATION DOSAGE (FROM 50MG ONCE DAILY TO 100MG ONCE DAILY) WHICH STARTED ON 08OCT2020 HELPED WITH 'WORSENING OF HYPERTENSION',
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **21 Feb 2021 21:38:37**
Generated On: 10 Jun 2021 10:01:21

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **21 Feb 2021 21:38:37**
Generated On: 10 Jun 2021 10:01:21

AEID	USA-US100-2020-MRNA-1273-P30 1000008
Adverse event	DEATH (UNKNOWN CAUSE)
Was this a medically-attended AE?	Yes ☐ No ■
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	19 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	19 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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

Narrative

50 Y/O RANDOMIZED MALE WHO RECEIVED THE FIRST DOSE OF BLINDED MRNA-1273 OR PLACEBO FOR SARS-COV-2 VACCINATION ON 8/20/2020 AND HIS SECOND, FINAL DOSE OF STUDY DRUG, ON 09/17/ 2020. 11/30/2020 THE SITE SENT AN EMAIL TO INQUIRE ABOUT SEVERAL MISSED DIARY ENTRIES. THE SITE RECEIVED NOTIFICATION VIA EMAIL FROM HIS WIFE THAT THE SUBJECT HAD PASSED AWAY ON 11/19/2020. THE SITE CONTACTED THE WIFE AT THE NUMBER GIVEN IN THE EMAIL TO OBTAIN INFORMATION SURROUNDING THE SUBJECT'S DEATH. PER THE WIFE'S REPORT THE SUBJECT WAS (b) (6)

FDA-CBER-2022-1614-3443071

	THE CAUSE OF DEATH IS CURRENTLY LISTED AS PENDING ON THE DEATH CERTIFICATE LABS WERE OBTAINED AT THE CORONER'S OFFICE AND WILL BE SENT FOR PROCESSING WHICH PER WIFE'S REPORT CAN TAKE UP TO 90 DAYS. THE WIFE REPORTED THAT THE SUBJECT HAS BATTLED SEVER ALCOHOL ADDICTION AND MENTAL HEALTH ISSUES IN THE PAST WITH SUICIDAL TENDENCIES AND FEELS THAT THIS CONTRIBUTED TO THE SUBJECT'S DEATH.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

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

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

FDA-CBER-2022-1614-3443073

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

FDA-CBER-2022-1614-3443074

	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 2016
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 ■

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **21 Feb 2021 21:38:37**
Generated On: 10 Jun 2021 10:01:21

Name of Medication	LOSARTAN
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
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-2022-1614-3443076

	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 2014
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	08 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	METOPROLOL
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-2022-1614-3443078

	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 DEC 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **21 Feb 2021 21:38:37**
Generated On: 10 Jun 2021 10:01:21

Name of Medication	CLONIDINE
Prophylaxis	Yes ☐ No ■
Indication	INSOMNIA
Dose per administration	.1
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-2022-1614-3443080

	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 DEC 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **21 Feb 2021 21:38:37**
Generated On: 10 Jun 2021 10:01:21

Name of Medication	VITAMIN D3
Prophylaxis	Yes ☐ No ■
Indication	VITAMIN D3 DEFICIENCY
Dose per administration	1
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-2022-1614-3443082

	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 APR 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 ■

Name of Medication	BENADRYL
Prophylaxis	Yes ☐ No ■
Indication	ACID REFLUX WITH NAUSEA
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-2022-1614-3443084

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

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

FDA-CBER-2022-1614-3443086

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

Name of Medication	LOSARTAN
Prophylaxis	Yes ☐ No ■
Indication	WORSENING OF HYPERTENSION
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 ☐
	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)*	
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 ■

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **21 Feb 2021 21:38:37**
Generated On: 10 Jun 2021 10:01:21

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ■ No ☐
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	.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 ☐

FDA-CBER-2022-1614-3443090

	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)*	13 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	13 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 ☐

US3832237
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

Were any concomitant procedures performed?	Yes ☐
	No ■

If yes, please complete Concomitant Procedures form.

Date of study discontinuation/completion *(dd MMM yyyy)*	19 NOV 2020
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ■ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	
If reason for discontinuation is Death, main cause of death	Adverse event ■ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	19 NOV 2020
Was autopsy performed?	Yes ☐ No ☐ Unknown ■

FDA-CBER-2022-1614-3443093

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

SAEID	USA-US100-2020-MRNA-1273-P301000008
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

FDA-CBER-2022-1614-3443094

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form (1)
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

SAEID	USA-US100-2020-MRNA-1273-P301000008
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/DEC/2020 13:03
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-2022-1614-3443095

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form (2)
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

SAEID	USA-US100-2020-MRNA-1273-P301000008
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/DEC/2020 11:27
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-2022-1614-3443096

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form (3)
Data signed: (b) (4) **21 Feb 2021 21:38:38**
Generated On: 10 Jun 2021 10:01:21

SAEID	USA-US100-2020-MRNA-1273-P301000008
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/JAN/2021 07:46
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

US3832237
Form: Participant Creation
Generated On: 10 Jun 2021 10:01:21
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'US3832237'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:54:59

US3832237
Form: Participant Creation
Generated On: 10 Jun 2021 10:01:21

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59

FDA-CBER-2022-1614-3443100

US3832237
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:26

US3832237
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Date of Visit is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Visit is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:55:00

US3832237
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:26

US3832237
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'SCRN'	System	20 Aug 2020 15:16:26

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US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:55:02

FDA-CBER-2022-1614-3443105

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '50'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'YEARS'	System	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '50'	System	20 Aug 2020 15:16:53

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Male (M)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

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US3832237
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:01:21
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:39

US3832237
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:01:21
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '20 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:53

FDA-CBER-2022-1614-3443120

US3832237
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:01:21
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'Aug 2020'	System	20 Aug 2020 15:16:53

US3832237
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:01:21
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '2020'	System	20 Aug 2020 15:16:53

FDA-CBER-2022-1614-3443122

US3832237
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:01:21
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Amendment 2 (2)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:53

US3832237
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:01:21
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:53

US3832237
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:01:21
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:53

US3832237
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:01:21
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:53

US3832237
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:01:21
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:53

US3832237
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:01:21
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:55:00

FDA-CBER-2022-1614-3443128

US3832237
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:01:21
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:16:57

FDA-CBER-2022-1614-3443129

US3832237
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 10:01:21
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:16:57

US3832237
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 10:01:21
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:02

FDA-CBER-2022-1614-3443131

US3832237
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:01:21
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:18:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:18:24
Data point term sent to Coder	System	20 Aug 2020 15:17:24
User entered 'Anxiety'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:15

FDA-CBER-2022-1614-3443132

US3832237
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:01:21
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'un UNK 1978'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:15

FDA-CBER-2022-1614-3443133

US3832237
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:15

US3832237
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:01:21
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:15

FDA-CBER-2022-1614-3443135

US3832237
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:01:21
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:15

US3832237
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:01:21
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:15

FDA-CBER-2022-1614-3443137

US3832237
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:01:21
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'Jan 1978'	System	20 Aug 2020 15:17:15

FDA-CBER-2022-1614-3443138

US3832237
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:01:21
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1978'	System	20 Aug 2020 15:17:15

US3832237
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:01:21
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	20 Aug 2020 15:17:15

FDA-CBER-2022-1614-3443140

US3832237
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:01:21
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	20 Aug 2020 15:17:15

FDA-CBER-2022-1614-3443141

US3832237
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:01:21
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
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)	20 Aug 2020 15:19:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:19:21
Data point term sent to Coder	System	20 Aug 2020 15:18:25
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:25

US3832237
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:01:21
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'un UNK 2014'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:25

FDA-CBER-2022-1614-3443143

US3832237
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:25

US3832237
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:01:21
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:25

FDA-CBER-2022-1614-3443145

US3832237
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:01:21
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:25

US3832237
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:01:21
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:25

US3832237
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:01:21
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'Jan 2014'	System	20 Aug 2020 15:17:25

FDA-CBER-2022-1614-3443148

US3832237
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:01:21
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '2014'	System	20 Aug 2020 15:17:25

FDA-CBER-2022-1614-3443149

US3832237
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:01:21
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	20 Aug 2020 15:17:25

FDA-CBER-2022-1614-3443150

US3832237
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:01:21
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	20 Aug 2020 15:17:25

FDA-CBER-2022-1614-3443151

US3832237
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:01:21
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:19:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:19:22
Data point term sent to Coder	System	20 Aug 2020 15:18:24
User entered 'Insomnia'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:36

FDA-CBER-2022-1614-3443152

US3832237
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:01:21
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'un UNK 2018'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:36

US3832237
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:36

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US3832237
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:01:21
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:36

FDA-CBER-2022-1614-3443155

US3832237
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:01:21
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:36

US3832237
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:01:21
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:36

FDA-CBER-2022-1614-3443157

US3832237
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:01:21
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'Jan 2018'	System	20 Aug 2020 15:17:36

US3832237
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:01:21
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '2018'	System	20 Aug 2020 15:17:36

US3832237
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:01:21
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	20 Aug 2020 15:17:36

FDA-CBER-2022-1614-3443160

US3832237
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:01:21
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	20 Aug 2020 15:17:36

FDA-CBER-2022-1614-3443161

US3832237
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:01:21
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:19:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:19:55
Data point term sent to Coder	System	20 Aug 2020 15:18:27
User entered 'Vitamin D Deficiency'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:55

US3832237
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:01:21
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User closed query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered 'un Dec 2019'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:55

US3832237
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:55

FDA-CBER-2022-1614-3443164

US3832237
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:01:21
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:55

US3832237
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:01:21
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:55

US3832237
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:01:21
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:17:55

US3832237
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:01:21
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'Dec 2019'	System	20 Aug 2020 15:17:55

FDA-CBER-2022-1614-3443168

US3832237
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:01:21
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '2019'	System	20 Aug 2020 15:17:55

US3832237
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:01:21
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	20 Aug 2020 15:17:55

FDA-CBER-2022-1614-3443170

US3832237
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:01:21
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	20 Aug 2020 15:17:55

US3832237
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:01:21
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 04:42:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 04:42:55
Data point term sent to Coder	System	02 Nov 2020 16:18:50
User entered 'Acid Reflux with Nausea'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:17:59

US3832237
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:01:21
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'UN UNK 2017'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:17:59

US3832237
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:17:59

FDA-CBER-2022-1614-3443174

US3832237
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:01:21
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:17:59

US3832237
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:01:21
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:17:59

FDA-CBER-2022-1614-3443176

US3832237
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:01:21
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:17:59

FDA-CBER-2022-1614-3443177

US3832237
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:01:21
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'Jan 2017'	System	02 Nov 2020 16:17:59

US3832237
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:01:21
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '2017'	System	02 Nov 2020 16:17:59

FDA-CBER-2022-1614-3443179

US3832237
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:01:21
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	02 Nov 2020 16:17:59

FDA-CBER-2022-1614-3443180

US3832237
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:01:21
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	02 Nov 2020 16:17:59

FDA-CBER-2022-1614-3443181

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '20 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '11:12'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '20 Aug 2020 11:12'	System	20 Aug 2020 15:53:16

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '173.4' cm	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16
DataPoint set to visible.	System	20 Aug 2020 15:16:57

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '89.4' kg	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16
DataPoint set to visible.	System	20 Aug 2020 15:16:57

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
Amendment Manager: User entered '29.73304'	System	17 Sep 2020 00:15:55
User entered '29.7'	System	20 Aug 2020 15:53:16
DataPoint set to visible.	System	20 Aug 2020 15:16:57

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'kg/m2'	System	20 Aug 2020 15:53:16
DataPoint set to visible.	System	20 Aug 2020 15:16:57

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '98.0' F	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '67'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'bpm'	System	20 Aug 2020 15:53:16

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US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '16'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'breaths/min'	System	20 Aug 2020 15:53:16

FDA-CBER-2022-1614-3443196

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:27:21
User closed query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 07:17:17
Query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' answered with 'Noted as abnormal NCS per Sub-I' (Site from System).	Danyel Johnson (b) (4) (b) (4)	24 Sep 2020 16:46:55
User opened query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	System	20 Aug 2020 15:53:16
User entered '173'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16

FDA-CBER-2022-1614-3443197

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	20 Aug 2020 15:53:16

FDA-CBER-2022-1614-3443198

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '99'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:16

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	20 Aug 2020 15:53:16

FDA-CBER-2022-1614-3443200

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59

FDA-CBER-2022-1614-3443201

US3832237
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59

FDA-CBER-2022-1614-3443202

US3832237
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 10:01:21
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:18:17

US3832237
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 10:01:21
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Physical Examination Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User closed query 'Physical Examination is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Physical Examination Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User opened query 'Physical Examination is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '20 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:18:17

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 15:00:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 15:00:05
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	24 Sep 2020 15:00:05
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 15:19:08
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:01:21
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:27:21
User entered 'Plans on routinely (e.g., weekly) going to places where people gather (e.g., places of worship, restaurants, bars, sporting events) over the coming months'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:19:08

US3832237
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:28

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US3832237
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Date of Visit is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Visit is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '20 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:28

US3832237
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:28

US3832237
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'VISIT1'	System	20 Aug 2020 15:53:28

FDA-CBER-2022-1614-3443229

US3832237
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:01:21
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Date of Randomization is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Randomization is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:34:59

US3832237
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:01:21
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:51:02
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:51:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 15:34:59
User entered '106302' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:34:59

US3832237
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:01:21
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:34:59

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US3832237
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:33:00

US3832237
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:33:00

US3832237
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:01:21
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:33:00

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US3832237
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:01:21
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:33:00

US3832237
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:01:21
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:33:00

US3832237
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:01:21
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:27:21
User closed query 'please enter data' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:45:38
Query 'please enter data' answered with 'Data updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	28 Nov 2020 23:53:34
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	28 Nov 2020 23:53:26
User opened query 'please enter data' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 20:24:51
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:50
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:43:33

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:01:21
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:10:07
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' answered with 'UPDATED' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:22:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:22:34
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:14:55
User entered '173.4' cm	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:01:21
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:22:34
User entered '89.4' kg	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:01:21
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:10:07
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' answered with 'UPDATED' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:22:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:22:34
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:14:55
User entered '173.4' cm	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:01:21
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:22:34
User entered '89.4' kg	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '20 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '11:12'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

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US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '20 Aug 2020 11:12'	System	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '98.0' F	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

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US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '67'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'bpm'	System	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '16'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'breaths/min'	System	20 Aug 2020 16:41:56

FDA-CBER-2022-1614-3443254

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:15:55
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Sep 2020 00:15:55
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	17 Sep 2020 00:15:54
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Aug 2020 16:41:56
User entered '173'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	20 Aug 2020 16:41:56

FDA-CBER-2022-1614-3443256

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '99'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

FDA-CBER-2022-1614-3443257

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	20 Aug 2020 16:41:56

FDA-CBER-2022-1614-3443258

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:01:21
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:27:21
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:10:07
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' answered with 'UPDATED' (Site from DM).	Danyel Johnson (b) (4)	14 Dec 2020 21:22:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	14 Dec 2020 21:22:34
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:14:55
User entered '173.4' cm	Alyssa-Kay Peay (b) (4)	20 Aug 2020 16:41:56

FDA-CBER-2022-1614-3443259

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:01:21
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:22:34
User entered '89.4' kg	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '20 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:00
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	20 Aug 2020 16:41:56
User entered '12:25'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '20 Aug 2020 12:25'	System	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '98.0' F	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '70'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'bpm'	System	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '16'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'breaths/min'	System	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:15:55
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Sep 2020 00:15:55
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	17 Sep 2020 00:15:54
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Aug 2020 16:41:56
User entered '164'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	20 Aug 2020 16:41:56

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US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	17 Sep 2020 00:15:54
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Aug 2020 16:41:56
User entered '105'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	20 Aug 2020 16:41:56

US3832237
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 10:01:21
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:39

US3832237
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 10:01:21
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Physical Examination Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User closed query 'Physical Examination is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Physical Examination Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User opened query 'Physical Examination is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '20 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:39

US3832237
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:01:11

US3832237
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:01:11

US3832237
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:01:11

US3832237
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 16:01:11

US3832237
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Start Date is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Start Date is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '20 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:01:11

US3832237
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '11:55'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:01:11

US3832237
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '20 Aug 2020 11:55'	System	20 Aug 2020 16:01:11

US3832237
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 16:01:11

US3832237
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'ONCE'	System	20 Aug 2020 16:01:11

US3832237
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 16:01:11

US3832237
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:53

US3832237
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Collection date is after date of death. Please update as appropriate.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Collection date is after date of death. Please update as appropriate.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '20 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:53

US3832237
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '11:33'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:53:53

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US3832237
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '20 Aug 2020 11:33'	System	20 Aug 2020 15:53:53

US3832237
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 10:01:21
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Collection Date is after date of death. Please update as appropriate.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Collection Date is after date of death. Please update as appropriate.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '20 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:07

US3832237
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:01:21
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:07

US3832237
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:01:21
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:07

US3832237
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:01:21
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '11:27'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:07

US3832237
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:01:21
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '20 Aug 2020 11:27'	System	20 Aug 2020 15:54:07

US3832237
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:01:21
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:07

US3832237
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:01:21
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	11 Nov 2020 19:44:04
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:07

US3832237
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:01:21
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	11 Nov 2020 19:44:04
User entered '11:27'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:07

US3832237
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:01:21
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	11 Nov 2020 19:44:04
User entered '20 Aug 2020 11:27'	System	20 Aug 2020 15:54:07

US3832237
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:11

US3832237
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:54:11

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:27:25', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'b4cc4625-9e65-4f67-b61b-f707002dec87'	System	20 Aug 2020 16:27:48
User entered 'Yes (Y)'	System	20 Aug 2020 16:27:48

FDA-CBER-2022-1614-3443305

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:27:35', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'b4cc4625-9e65-4f67-b61b-f707002dec87'	System	20 Aug 2020 16:27:48
User entered '98.0'	System	20 Aug 2020 16:27:48

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:27:39', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'b4cc4625-9e65-4f67-b61b-f707002dec87'	System	20 Aug 2020 16:27:48
User entered 'No (N)'	System	20 Aug 2020 16:27:48

FDA-CBER-2022-1614-3443307

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:27:44', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'b4cc4625-9e65-4f67-b61b-f707002dec87'	System	20 Aug 2020 16:27:48
User entered '20 Aug 2020 12:27'	System	20 Aug 2020 16:27:48

FDA-CBER-2022-1614-3443308

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Aug 2020 12:15'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443309

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Aug 2020 14:45'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443310

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:06:08', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '966f1b28-a663-44f4-871e-58399b9901d6'	System	20 Aug 2020 22:06:42
User entered 'Yes (Y)'	System	20 Aug 2020 22:06:42

FDA-CBER-2022-1614-3443312

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:06:23', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '966f1b28-a663-44f4-871e-58399b9901d6'	System	20 Aug 2020 22:06:42
User entered '97.7'	System	20 Aug 2020 22:06:42

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:06:28', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '966f1b28-a663-44f4-871e-58399b9901d6'	System	20 Aug 2020 22:06:42
User entered 'No (N)'	System	20 Aug 2020 22:06:42

FDA-CBER-2022-1614-3443314

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:06:36', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '966f1b28-a663-44f4-871e-58399b9901d6'	System	20 Aug 2020 22:06:42
User entered '20 Aug 2020 18:06'	System	20 Aug 2020 22:06:42

FDA-CBER-2022-1614-3443315

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Aug 2020 15:40'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443316

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443317

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 2'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443318

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:00', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2805223d-02bc-4332-9fce-48ec37650ee5'	System	21 Aug 2020 22:27:21
User entered 'Yes (Y)'	System	21 Aug 2020 22:27:21

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:08', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2805223d-02bc-4332-9fce-48ec37650ee5'	System	21 Aug 2020 22:27:21
User entered '96.7'	System	21 Aug 2020 22:27:21

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:12', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2805223d-02bc-4332-9fce-48ec37650ee5'	System	21 Aug 2020 22:27:21
User entered 'No (N)'	System	21 Aug 2020 22:27:21

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:19', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2805223d-02bc-4332-9fce-48ec37650ee5'	System	21 Aug 2020 22:27:21
User entered '21 Aug 2020 18:27'	System	21 Aug 2020 22:27:21

FDA-CBER-2022-1614-3443322

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443323

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443324

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 3'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:04:49', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd793b14e-79a4-4228-9493-36e18a685586'	System	22 Aug 2020 22:06:05
User entered 'Yes (Y)'	System	22 Aug 2020 22:06:05

FDA-CBER-2022-1614-3443326

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:05:52', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd793b14e-79a4-4228-9493-36e18a685586'	System	22 Aug 2020 22:06:05
User entered '97.6'	System	22 Aug 2020 22:06:05

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:05:56', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd793b14e-79a4-4228-9493-36e18a685586'	System	22 Aug 2020 22:06:05
User entered 'No (N)'	System	22 Aug 2020 22:06:05

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:02', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd793b14e-79a4-4228-9493-36e18a685586'	System	22 Aug 2020 22:06:05
User entered '22 Aug 2020 18:06'	System	22 Aug 2020 22:06:05

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443330

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 4'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:54:20', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8d86362e-1f21-4df2-9ea7-387171b43a42'	System	23 Aug 2020 21:55:40
User entered 'Yes (Y)'	System	23 Aug 2020 21:55:40

FDA-CBER-2022-1614-3443333

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:55:29', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8d86362e-1f21-4df2-9ea7-387171b43a42'	System	23 Aug 2020 21:55:40
User entered '97.1'	System	23 Aug 2020 21:55:40

FDA-CBER-2022-1614-3443334

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:55:32', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8d86362e-1f21-4df2-9ea7-387171b43a42'	System	23 Aug 2020 21:55:40
User entered 'No (N)'	System	23 Aug 2020 21:55:40

FDA-CBER-2022-1614-3443335

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:55:38', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8d86362e-1f21-4df2-9ea7-387171b43a42'	System	23 Aug 2020 21:55:40
User entered '23 Aug 2020 17:55'	System	23 Aug 2020 21:55:40

FDA-CBER-2022-1614-3443336

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443337

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443338

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 5'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:27:57', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'adf7be51-f504-4dc5-aac5-62e620a33ee3'	System	25 Aug 2020 03:28:56
User entered 'Yes (Y)'	System	25 Aug 2020 03:28:56

FDA-CBER-2022-1614-3443340

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:28:46', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'adf7be51-f504-4dc5-aac5-62e620a33ee3'	System	25 Aug 2020 03:28:56
User entered '97.5'	System	25 Aug 2020 03:28:56

FDA-CBER-2022-1614-3443341

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:28:49', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'adf7be51-f504-4dc5-aac5-62e620a33ee3'	System	25 Aug 2020 03:28:56
User entered 'No (N)'	System	25 Aug 2020 03:28:56

FDA-CBER-2022-1614-3443342

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:28:53', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'adf7be51-f504-4dc5-aac5-62e620a33ee3'	System	25 Aug 2020 03:28:56
User entered '24 Aug 2020 23:28'	System	25 Aug 2020 03:28:56

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443344

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443345

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 6'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:13:26', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '3eaa2b41-1171-4c02-99ea-4c2881ab931c'	System	25 Aug 2020 22:13:45
User entered 'Yes (Y)'	System	25 Aug 2020 22:13:45

FDA-CBER-2022-1614-3443347

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:13:34', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '3eaa2b41-1171-4c02-99ea-4c2881ab931c'	System	25 Aug 2020 22:13:45
User entered '97.3'	System	25 Aug 2020 22:13:45

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:13:38', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '3eaa2b41-1171-4c02-99ea-4c2881ab931c'	System	25 Aug 2020 22:13:45
User entered 'No (N)'	System	25 Aug 2020 22:13:45

FDA-CBER-2022-1614-3443349

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:13:43', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '3eaa2b41-1171-4c02-99ea-4c2881ab931c'	System	25 Aug 2020 22:13:45
User entered '25 Aug 2020 18:13'	System	25 Aug 2020 22:13:45

FDA-CBER-2022-1614-3443350

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443351

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443352

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 7'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:08:24', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd8e80b98-47b6-4ec0-8051-a6a692c501d7'	System	26 Aug 2020 21:08:38
User entered 'Yes (Y)'	System	26 Aug 2020 21:08:38

FDA-CBER-2022-1614-3443354

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:08:29', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd8e80b98-47b6-4ec0-8051-a6a692c501d7'	System	26 Aug 2020 21:08:38
User entered '98.1'	System	26 Aug 2020 21:08:38

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:08:32', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd8e80b98-47b6-4ec0-8051-a6a692c501d7'	System	26 Aug 2020 21:08:38
User entered 'No (N)'	System	26 Aug 2020 21:08:38

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:08:35', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd8e80b98-47b6-4ec0-8051-a6a692c501d7'	System	26 Aug 2020 21:08:38
User entered '26 Aug 2020 17:08'	System	26 Aug 2020 21:08:38

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443358

US3832237
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443359

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:27:54', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '99838d5c-b0e3-4ec2-852a-021f51862dbd'	System	20 Aug 2020 16:28:24
User entered 'None (1)'	System	20 Aug 2020 16:28:24

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:10', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '99838d5c-b0e3-4ec2-852a-021f51862dbd'	System	20 Aug 2020 16:28:24
User entered 'No (N)'	System	20 Aug 2020 16:28:24

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:14', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '99838d5c-b0e3-4ec2-852a-021f51862dbd'	System	20 Aug 2020 16:28:24
User entered 'No (N)'	System	20 Aug 2020 16:28:24

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:18', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '99838d5c-b0e3-4ec2-852a-021f51862dbd'	System	20 Aug 2020 16:28:24
User entered 'None (1)'	System	20 Aug 2020 16:28:24

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:22', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '99838d5c-b0e3-4ec2-852a-021f51862dbd'	System	20 Aug 2020 16:28:24
User entered '20 Aug 2020 12:28'	System	20 Aug 2020 16:28:24

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US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Aug 2020 12:15'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443366

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Aug 2020 14:45'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443367

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:06:42', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2b15ef1e-fc51-406d-83a1-29f89e2f7ba5'	System	20 Aug 2020 22:07:03
User entered 'None (1)'	System	20 Aug 2020 22:07:03

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:06:46', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2b15ef1e-fc51-406d-83a1-29f89e2f7ba5'	System	20 Aug 2020 22:07:03
User entered 'No (N)'	System	20 Aug 2020 22:07:03

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:06:50', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2b15ef1e-fc51-406d-83a1-29f89e2f7ba5'	System	20 Aug 2020 22:07:03
User entered 'No (N)'	System	20 Aug 2020 22:07:03

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:06:54', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2b15ef1e-fc51-406d-83a1-29f89e2f7ba5'	System	20 Aug 2020 22:07:03
User entered 'None (1)'	System	20 Aug 2020 22:07:03

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US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:06:58', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2b15ef1e-fc51-406d-83a1-29f89e2f7ba5'	System	20 Aug 2020 22:07:03
User entered '20 Aug 2020 18:06'	System	20 Aug 2020 22:07:03

FDA-CBER-2022-1614-3443373

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Aug 2020 15:40'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443374

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443375

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 2'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:29', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a587142c-88c9-44e0-b619-4c3ba38f73c9'	System	21 Aug 2020 22:27:45
User entered 'None (1)'	System	21 Aug 2020 22:27:45

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:32', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a587142c-88c9-44e0-b619-4c3ba38f73c9'	System	21 Aug 2020 22:27:45
User entered 'No (N)'	System	21 Aug 2020 22:27:45

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:34', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a587142c-88c9-44e0-b619-4c3ba38f73c9'	System	21 Aug 2020 22:27:45
User entered 'No (N)'	System	21 Aug 2020 22:27:45

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:38', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a587142c-88c9-44e0-b619-4c3ba38f73c9'	System	21 Aug 2020 22:27:45
User entered 'None (1)'	System	21 Aug 2020 22:27:45

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:42', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a587142c-88c9-44e0-b619-4c3ba38f73c9'	System	21 Aug 2020 22:27:45
User entered '21 Aug 2020 18:27'	System	21 Aug 2020 22:27:45

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US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443382

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 3'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443384

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:08', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'db3ab07e-a988-4bb8-8846-dc489632f5a4'	System	22 Aug 2020 22:06:31
User entered 'None (1)'	System	22 Aug 2020 22:06:31

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:17', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'db3ab07e-a988-4bb8-8846-dc489632f5a4'	System	22 Aug 2020 22:06:31
User entered 'No (N)'	System	22 Aug 2020 22:06:31

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:19', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'db3ab07e-a988-4bb8-8846-dc489632f5a4'	System	22 Aug 2020 22:06:31
User entered 'No (N)'	System	22 Aug 2020 22:06:31

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:24', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'db3ab07e-a988-4bb8-8846-dc489632f5a4'	System	22 Aug 2020 22:06:31
User entered 'None (1)'	System	22 Aug 2020 22:06:31

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:27', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'db3ab07e-a988-4bb8-8846-dc489632f5a4'	System	22 Aug 2020 22:06:31
User entered '22 Aug 2020 18:06'	System	22 Aug 2020 22:06:31

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US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443390

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443391

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 4'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443392

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:25', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '21b0d0b5-ebe5-43f2-9901-607dc67d791e'	System	23 Aug 2020 21:53:41
User entered 'None (1)'	System	23 Aug 2020 21:53:41

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:28', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '21b0d0b5-ebe5-43f2-9901-607dc67d791e'	System	23 Aug 2020 21:53:41
User entered 'No (N)'	System	23 Aug 2020 21:53:41

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:32', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '21b0d0b5-ebe5-43f2-9901-607dc67d791e'	System	23 Aug 2020 21:53:41
User entered 'No (N)'	System	23 Aug 2020 21:53:41

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:34', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '21b0d0b5-ebe5-43f2-9901-607dc67d791e'	System	23 Aug 2020 21:53:41
User entered 'None (1)'	System	23 Aug 2020 21:53:41

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:37', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '21b0d0b5-ebe5-43f2-9901-607dc67d791e'	System	23 Aug 2020 21:53:41
User entered '23 Aug 2020 17:53'	System	23 Aug 2020 21:53:41

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US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443398

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443399

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 5'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443400

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:28:58', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '09461dff-4553-4f56-9e9b-4b70196995b2'	System	25 Aug 2020 03:29:12
User entered 'None (1)'	System	25 Aug 2020 03:29:12

FDA-CBER-2022-1614-3443401

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:00', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '09461dff-4553-4f56-9e9b-4b70196995b2'	System	25 Aug 2020 03:29:12
User entered 'No (N)'	System	25 Aug 2020 03:29:12

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:03', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '09461dff-4553-4f56-9e9b-4b70196995b2'	System	25 Aug 2020 03:29:12
User entered 'No (N)'	System	25 Aug 2020 03:29:12

FDA-CBER-2022-1614-3443403

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:06', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '09461dff-4553-4f56-9e9b-4b70196995b2'	System	25 Aug 2020 03:29:12
User entered 'None (1)'	System	25 Aug 2020 03:29:12

FDA-CBER-2022-1614-3443404

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:09', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '09461dff-4553-4f56-9e9b-4b70196995b2'	System	25 Aug 2020 03:29:12
User entered '24 Aug 2020 23:29'	System	25 Aug 2020 03:29:12

FDA-CBER-2022-1614-3443405

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443406

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443407

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 6'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443408

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:10:57', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '225a67ae-23a2-4468-b285-2f9880238220'	System	25 Aug 2020 22:11:12
User entered 'None (1)'	System	25 Aug 2020 22:11:12

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:10:59', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '225a67ae-23a2-4468-b285-2f9880238220'	System	25 Aug 2020 22:11:12
User entered 'No (N)'	System	25 Aug 2020 22:11:12

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:11:02', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '225a67ae-23a2-4468-b285-2f9880238220'	System	25 Aug 2020 22:11:12
User entered 'No (N)'	System	25 Aug 2020 22:11:12

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:11:06', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '225a67ae-23a2-4468-b285-2f9880238220'	System	25 Aug 2020 22:11:12
User entered 'None (1)'	System	25 Aug 2020 22:11:12

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:11:09', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '225a67ae-23a2-4468-b285-2f9880238220'	System	25 Aug 2020 22:11:12
User entered '25 Aug 2020 18:11'	System	25 Aug 2020 22:11:12

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

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US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443415

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 7'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:04:37', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5fb3a5f6-7c9f-47d3-a9ac-fa8738055f9b'	System	26 Aug 2020 21:04:55
User entered 'None (1)'	System	26 Aug 2020 21:04:55

FDA-CBER-2022-1614-3443417

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:04:43', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5fb3a5f6-7c9f-47d3-a9ac-fa8738055f9b'	System	26 Aug 2020 21:04:55
User entered 'No (N)'	System	26 Aug 2020 21:04:55

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:04:46', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5fb3a5f6-7c9f-47d3-a9ac-fa8738055f9b'	System	26 Aug 2020 21:04:55
User entered 'No (N)'	System	26 Aug 2020 21:04:55

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:04:50', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5fb3a5f6-7c9f-47d3-a9ac-fa8738055f9b'	System	26 Aug 2020 21:04:55
User entered 'None (1)'	System	26 Aug 2020 21:04:55

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US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:04:52', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5fb3a5f6-7c9f-47d3-a9ac-fa8738055f9b'	System	26 Aug 2020 21:04:55
User entered '26 Aug 2020 17:04'	System	26 Aug 2020 21:04:55

FDA-CBER-2022-1614-3443421

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443423

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443424

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:26', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '258a808c-af2c-462c-ac89-23f5a9e5a5fc'	System	20 Aug 2020 16:28:48
User entered 'None (0)'	System	20 Aug 2020 16:28:48

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:29', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '258a808c-af2c-462c-ac89-23f5a9e5a5fc'	System	20 Aug 2020 16:28:48
User entered 'None (0)'	System	20 Aug 2020 16:28:48

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:30', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '258a808c-af2c-462c-ac89-23f5a9e5a5fc'	System	20 Aug 2020 16:28:48
User entered 'None (0)'	System	20 Aug 2020 16:28:48

FDA-CBER-2022-1614-3443427

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:33', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '258a808c-af2c-462c-ac89-23f5a9e5a5fc'	System	20 Aug 2020 16:28:48
User entered 'None (0)'	System	20 Aug 2020 16:28:48

FDA-CBER-2022-1614-3443428

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:35', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '258a808c-af2c-462c-ac89-23f5a9e5a5fc'	System	20 Aug 2020 16:28:48
User entered 'None (0)'	System	20 Aug 2020 16:28:48

FDA-CBER-2022-1614-3443429

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:38', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '258a808c-af2c-462c-ac89-23f5a9e5a5fc'	System	20 Aug 2020 16:28:48
User entered 'None (0)'	System	20 Aug 2020 16:28:48

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:41', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '258a808c-af2c-462c-ac89-23f5a9e5a5fc'	System	20 Aug 2020 16:28:48
User entered 'No (N)'	System	20 Aug 2020 16:28:48

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T12:28:44', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '258a808c-af2c-462c-ac89-23f5a9e5a5fc'	System	20 Aug 2020 16:28:48
User entered '20 Aug 2020 12:28'	System	20 Aug 2020 16:28:48

FDA-CBER-2022-1614-3443432

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Aug 2020 12:15'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Aug 2020 14:45'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443434

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443435

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:07:05', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '120c19a4-e43c-4861-8ad1-c0de450eb5f7'	System	20 Aug 2020 22:07:32
User entered 'None (0)'	System	20 Aug 2020 22:07:32

FDA-CBER-2022-1614-3443436

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:07:08', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '120c19a4-e43c-4861-8ad1-c0de450eb5f7'	System	20 Aug 2020 22:07:32
User entered 'None (0)'	System	20 Aug 2020 22:07:32

FDA-CBER-2022-1614-3443437

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:07:11', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '120c19a4-e43c-4861-8ad1-c0de450eb5f7'	System	20 Aug 2020 22:07:32
User entered 'None (0)'	System	20 Aug 2020 22:07:32

FDA-CBER-2022-1614-3443438

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:07:13', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '120c19a4-e43c-4861-8ad1-c0de450eb5f7'	System	20 Aug 2020 22:07:32
User entered 'None (0)'	System	20 Aug 2020 22:07:32

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:07:16', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '120c19a4-e43c-4861-8ad1-c0de450eb5f7'	System	20 Aug 2020 22:07:32
User entered 'None (0)'	System	20 Aug 2020 22:07:32

FDA-CBER-2022-1614-3443440

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:07:19', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '120c19a4-e43c-4861-8ad1-c0de450eb5f7'	System	20 Aug 2020 22:07:32
User entered 'None (0)'	System	20 Aug 2020 22:07:32

FDA-CBER-2022-1614-3443441

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:07:25', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '120c19a4-e43c-4861-8ad1-c0de450eb5f7'	System	20 Aug 2020 22:07:32
User entered 'No (N)'	System	20 Aug 2020 22:07:32

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-20T18:07:30', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '120c19a4-e43c-4861-8ad1-c0de450eb5f7'	System	20 Aug 2020 22:07:32
User entered '20 Aug 2020 18:07'	System	20 Aug 2020 22:07:32

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Aug 2020 15:40'	System	20 Aug 2020 16:01:11

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US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443445

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 2'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443446

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:46', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ecd06572-78f5-4703-9adc-8ff91414a9db'	System	21 Aug 2020 22:28:08
User entered 'None (0)'	System	21 Aug 2020 22:28:08

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:48', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ecd06572-78f5-4703-9adc-8ff91414a9db'	System	21 Aug 2020 22:28:08
User entered 'None (0)'	System	21 Aug 2020 22:28:08

FDA-CBER-2022-1614-3443448

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:50', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ecd06572-78f5-4703-9adc-8ff91414a9db'	System	21 Aug 2020 22:28:08
User entered 'None (0)'	System	21 Aug 2020 22:28:08

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:53', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ecd06572-78f5-4703-9adc-8ff91414a9db'	System	21 Aug 2020 22:28:08
User entered 'None (0)'	System	21 Aug 2020 22:28:08

FDA-CBER-2022-1614-3443450

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:55', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ecd06572-78f5-4703-9adc-8ff91414a9db'	System	21 Aug 2020 22:28:08
User entered 'None (0)'	System	21 Aug 2020 22:28:08

FDA-CBER-2022-1614-3443451

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:27:58', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ecd06572-78f5-4703-9adc-8ff91414a9db'	System	21 Aug 2020 22:28:08
User entered 'None (0)'	System	21 Aug 2020 22:28:08

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:28:01', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ecd06572-78f5-4703-9adc-8ff91414a9db'	System	21 Aug 2020 22:28:08
User entered 'No (N)'	System	21 Aug 2020 22:28:08

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-21T18:28:04', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ecd06572-78f5-4703-9adc-8ff91414a9db'	System	21 Aug 2020 22:28:08
User entered '21 Aug 2020 18:28'	System	21 Aug 2020 22:28:08

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443455

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443456

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 3'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:32', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'fda8f5ed-b238-4448-8c69-3192f8c3ab8e'	System	22 Aug 2020 22:06:53
User entered 'None (0)'	System	22 Aug 2020 22:06:53

FDA-CBER-2022-1614-3443458

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:34', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'fda8f5ed-b238-4448-8c69-3192f8c3ab8e'	System	22 Aug 2020 22:06:53
User entered 'None (0)'	System	22 Aug 2020 22:06:53

FDA-CBER-2022-1614-3443459

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:36', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'fda8f5ed-b238-4448-8c69-3192f8c3ab8e'	System	22 Aug 2020 22:06:53
User entered 'None (0)'	System	22 Aug 2020 22:06:53

FDA-CBER-2022-1614-3443460

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:39', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'fda8f5ed-b238-4448-8c69-3192f8c3ab8e'	System	22 Aug 2020 22:06:53
User entered 'None (0)'	System	22 Aug 2020 22:06:53

FDA-CBER-2022-1614-3443461

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:41', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'fda8f5ed-b238-4448-8c69-3192f8c3ab8e'	System	22 Aug 2020 22:06:53
User entered 'None (0)'	System	22 Aug 2020 22:06:53

FDA-CBER-2022-1614-3443462

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:43', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'fda8f5ed-b238-4448-8c69-3192f8c3ab8e'	System	22 Aug 2020 22:06:53
User entered 'None (0)'	System	22 Aug 2020 22:06:53

FDA-CBER-2022-1614-3443463

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:48', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'fda8f5ed-b238-4448-8c69-3192f8c3ab8e'	System	22 Aug 2020 22:06:53
User entered 'No (N)'	System	22 Aug 2020 22:06:53

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-22T18:06:51', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'fda8f5ed-b238-4448-8c69-3192f8c3ab8e'	System	22 Aug 2020 22:06:53
User entered '22 Aug 2020 18:06'	System	22 Aug 2020 22:06:53

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443466

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443467

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 4'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443468

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:41', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5057ff8c-8398-4d3d-b4d1-2018b74630fd'	System	23 Aug 2020 21:54:00
User entered 'None (0)'	System	23 Aug 2020 21:54:00

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:43', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5057ff8c-8398-4d3d-b4d1-2018b74630fd'	System	23 Aug 2020 21:54:00
User entered 'None (0)'	System	23 Aug 2020 21:54:00

FDA-CBER-2022-1614-3443470

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:45', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5057ff8c-8398-4d3d-b4d1-2018b74630fd'	System	23 Aug 2020 21:54:00
User entered 'None (0)'	System	23 Aug 2020 21:54:00

FDA-CBER-2022-1614-3443471

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:47', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5057ff8c-8398-4d3d-b4d1-2018b74630fd'	System	23 Aug 2020 21:54:00
User entered 'None (0)'	System	23 Aug 2020 21:54:00

FDA-CBER-2022-1614-3443472

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:50', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5057ff8c-8398-4d3d-b4d1-2018b74630fd'	System	23 Aug 2020 21:54:00
User entered 'None (0)'	System	23 Aug 2020 21:54:00

FDA-CBER-2022-1614-3443473

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:52', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5057ff8c-8398-4d3d-b4d1-2018b74630fd'	System	23 Aug 2020 21:54:00
User entered 'None (0)'	System	23 Aug 2020 21:54:00

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:54', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5057ff8c-8398-4d3d-b4d1-2018b74630fd'	System	23 Aug 2020 21:54:00
User entered 'No (N)'	System	23 Aug 2020 21:54:00

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-23T17:53:57', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5057ff8c-8398-4d3d-b4d1-2018b74630fd'	System	23 Aug 2020 21:54:00
User entered '23 Aug 2020 17:53'	System	23 Aug 2020 21:54:00

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443477

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443478

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 5'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:13', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '97909130-d94f-4d4e-919e-1bb6c302df00'	System	25 Aug 2020 03:29:31
User entered 'None (0)'	System	25 Aug 2020 03:29:31

FDA-CBER-2022-1614-3443480

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:15', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '97909130-d94f-4d4e-919e-1bb6c302df00'	System	25 Aug 2020 03:29:31
User entered 'None (0)'	System	25 Aug 2020 03:29:31

FDA-CBER-2022-1614-3443481

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:17', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '97909130-d94f-4d4e-919e-1bb6c302df00'	System	25 Aug 2020 03:29:31
User entered 'None (0)'	System	25 Aug 2020 03:29:31

FDA-CBER-2022-1614-3443482

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:19', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '97909130-d94f-4d4e-919e-1bb6c302df00'	System	25 Aug 2020 03:29:31
User entered 'None (0)'	System	25 Aug 2020 03:29:31

FDA-CBER-2022-1614-3443483

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:21', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '97909130-d94f-4d4e-919e-1bb6c302df00'	System	25 Aug 2020 03:29:31
User entered 'None (0)'	System	25 Aug 2020 03:29:31

FDA-CBER-2022-1614-3443484

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:22', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '97909130-d94f-4d4e-919e-1bb6c302df00'	System	25 Aug 2020 03:29:31
User entered 'None (0)'	System	25 Aug 2020 03:29:31

FDA-CBER-2022-1614-3443485

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:25', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '97909130-d94f-4d4e-919e-1bb6c302df00'	System	25 Aug 2020 03:29:31
User entered 'No (N)'	System	25 Aug 2020 03:29:31

FDA-CBER-2022-1614-3443486

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-24T23:29:28', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '97909130-d94f-4d4e-919e-1bb6c302df00'	System	25 Aug 2020 03:29:31
User entered '24 Aug 2020 23:29'	System	25 Aug 2020 03:29:31

FDA-CBER-2022-1614-3443487

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443488

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443489

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 6'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443490

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:11:13', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'af1e44e0-ece2-4b46-8c3f-99ee9fd18e48'	System	25 Aug 2020 22:11:42
User entered 'None (0)'	System	25 Aug 2020 22:11:42

FDA-CBER-2022-1614-3443491

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:11:21', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'af1e44e0-ece2-4b46-8c3f-99ee9fd18e48'	System	25 Aug 2020 22:11:42
User entered 'None (0)'	System	25 Aug 2020 22:11:42

FDA-CBER-2022-1614-3443492

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:11:24', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'af1e44e0-ece2-4b46-8c3f-99ee9fd18e48'	System	25 Aug 2020 22:11:42
User entered 'None (0)'	System	25 Aug 2020 22:11:42

FDA-CBER-2022-1614-3443493

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:11:26', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'af1e44e0-ece2-4b46-8c3f-99ee9fd18e48'	System	25 Aug 2020 22:11:42
User entered 'None (0)'	System	25 Aug 2020 22:11:42

FDA-CBER-2022-1614-3443494

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:11:28', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'af1e44e0-ece2-4b46-8c3f-99ee9fd18e48'	System	25 Aug 2020 22:11:42
User entered 'None (0)'	System	25 Aug 2020 22:11:42

FDA-CBER-2022-1614-3443495

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:11:31', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'af1e44e0-ece2-4b46-8c3f-99ee9fd18e48'	System	25 Aug 2020 22:11:42
User entered 'None (0)'	System	25 Aug 2020 22:11:42

FDA-CBER-2022-1614-3443496

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:11:33', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'af1e44e0-ece2-4b46-8c3f-99ee9fd18e48'	System	25 Aug 2020 22:11:42
User entered 'No (N)'	System	25 Aug 2020 22:11:42

FDA-CBER-2022-1614-3443497

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-25T18:11:37', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'af1e44e0-ece2-4b46-8c3f-99ee9fd18e48'	System	25 Aug 2020 22:11:42
User entered '25 Aug 2020 18:11'	System	25 Aug 2020 22:11:42

FDA-CBER-2022-1614-3443498

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443499

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 7'	System	20 Aug 2020 16:01:11

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:04:58', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '22f78e29-755a-49d4-a9d5-1d3055a0449f'	System	26 Aug 2020 21:05:28
User entered 'None (0)'	System	26 Aug 2020 21:05:28

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:05:01', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '22f78e29-755a-49d4-a9d5-1d3055a0449f'	System	26 Aug 2020 21:05:28
User entered 'None (0)'	System	26 Aug 2020 21:05:28

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:05:04', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '22f78e29-755a-49d4-a9d5-1d3055a0449f'	System	26 Aug 2020 21:05:28
User entered 'None (0)'	System	26 Aug 2020 21:05:28

FDA-CBER-2022-1614-3443504

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:05:07', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '22f78e29-755a-49d4-a9d5-1d3055a0449f'	System	26 Aug 2020 21:05:28
User entered 'None (0)'	System	26 Aug 2020 21:05:28

FDA-CBER-2022-1614-3443505

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:05:10', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '22f78e29-755a-49d4-a9d5-1d3055a0449f'	System	26 Aug 2020 21:05:28
User entered 'None (0)'	System	26 Aug 2020 21:05:28

FDA-CBER-2022-1614-3443506

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:05:13', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '22f78e29-755a-49d4-a9d5-1d3055a0449f'	System	26 Aug 2020 21:05:28
User entered 'None (0)'	System	26 Aug 2020 21:05:28

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:05:18', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '22f78e29-755a-49d4-a9d5-1d3055a0449f'	System	26 Aug 2020 21:05:28
User entered 'No (N)'	System	26 Aug 2020 21:05:28

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-08-26T17:05:22', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '22f78e29-755a-49d4-a9d5-1d3055a0449f'	System	26 Aug 2020 21:05:28
User entered '26 Aug 2020 17:05'	System	26 Aug 2020 21:05:28

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443510

US3832237
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:01:11

FDA-CBER-2022-1614-3443511

US3832237
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	27 Aug 2020 13:45:24

US3832237
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '27 Aug 2020'	Emma Partin (b) (4) (b) (4)	27 Aug 2020 13:45:24

US3832237
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4) (b) (4)	27 Aug 2020 13:45:24

US3832237
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	Emma Partin (b) (4) (b) (4)	27 Aug 2020 13:45:24

FDA-CBER-2022-1614-3443515

US3832237
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	27 Aug 2020 13:45:31

US3832237
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	27 Aug 2020 13:45:31

FDA-CBER-2022-1614-3443517

US3832237
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 15:14:55

US3832237
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '3 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 15:14:55

US3832237
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 15:14:55

US3832237
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 15:14:55

US3832237
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 15:14:59

US3832237
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	16 Sep 2020 15:14:59

US3832237
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 15:15:07

US3832237
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '10 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 15:15:07

US3832237
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 15:15:07

US3832237
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 15:15:07

US3832237
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 15:15:10

US3832237
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	16 Sep 2020 15:15:10

US3832237
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:08:38

US3832237
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Date of Visit is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Visit is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '17 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:08:38

US3832237
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:08:38

US3832237
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'VISIT2'	System	17 Sep 2020 14:08:38

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US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '17 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '10:14'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443537

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '17 Sep 2020 10:14'	System	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443538

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '97.7' F	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443540

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '71'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'bpm'	System	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443543

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '16'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443544

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'breaths/min'	System	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443545

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '150'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443546

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443547

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '98'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443548

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443549

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443550

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '17 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '11:00'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443553

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '17 Sep 2020 11:00'	System	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443554

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '98.1' F	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443555

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '60'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'bpm'	System	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443559

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '15'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'breaths/min'	System	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443561

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '134'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443563

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '92'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443564

US3832237
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	17 Sep 2020 15:24:44

FDA-CBER-2022-1614-3443565

US3832237
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:01:21
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:08:43

US3832237
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:01:21
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Physical Examination Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User closed query 'Physical Examination is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Physical Examination Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User opened query 'Physical Examination is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '17 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:08:43

US3832237
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:05

US3832237
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:05

US3832237
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:05

US3832237
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 14:45:05

US3832237
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Start Date is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Start Date is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '17 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:05

US3832237
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '10:30'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:05

US3832237
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '17 Sep 2020 10:30'	System	17 Sep 2020 14:45:05

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US3832237
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:05

US3832237
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'ONCE'	System	17 Sep 2020 14:45:05

US3832237
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:01:21
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 14:45:05

US3832237
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:14

US3832237
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Collection date is after date of death. Please update as appropriate.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Collection date is after date of death. Please update as appropriate.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '17 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:14

US3832237
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '10:28'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:14

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US3832237
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '17 Sep 2020 10:28'	System	17 Sep 2020 14:45:14

US3832237
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 10:01:21
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Collection Date is after date of death. Please update as appropriate.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Collection Date is after date of death. Please update as appropriate.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '17 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:29

US3832237
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:01:21
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:29

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US3832237
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:01:21
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:29

US3832237
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:01:21
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '10:23'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:29

FDA-CBER-2022-1614-3443585

US3832237
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:01:21
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '17 Sep 2020 10:23'	System	17 Sep 2020 14:45:29

US3832237
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:01:21
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:29

US3832237
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:01:21
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	11 Nov 2020 19:44:17
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:29

US3832237
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:01:21
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	11 Nov 2020 19:44:17
User entered '10:23'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:45:29

US3832237
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:01:21
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	11 Nov 2020 19:44:17
User entered '17 Sep 2020 10:23'	System	17 Sep 2020 14:45:29

US3832237
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:08:48

US3832237
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	17 Sep 2020 14:08:48

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:01:40', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '9b89e5d9-1ab0-4814-bfcc-caf590ab7682'	System	17 Sep 2020 15:02:03
User entered 'Yes (Y)'	System	17 Sep 2020 15:02:03

FDA-CBER-2022-1614-3443594

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:01:47', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '9b89e5d9-1ab0-4814-bfcc-caf590ab7682'	System	17 Sep 2020 15:02:03
User entered '98.1'	System	17 Sep 2020 15:02:03

FDA-CBER-2022-1614-3443595

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:01:51', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '9b89e5d9-1ab0-4814-bfcc-caf590ab7682'	System	17 Sep 2020 15:02:03
User entered 'No (N)'	System	17 Sep 2020 15:02:03

FDA-CBER-2022-1614-3443596

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:01:58', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '9b89e5d9-1ab0-4814-bfcc-caf590ab7682'	System	17 Sep 2020 15:02:03
User entered '17 Sep 2020 11:01'	System	17 Sep 2020 15:02:03

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '17 Sep 2020 10:50'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443598

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '17 Sep 2020 13:20'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443599

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:55:21', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5949b6cf-efe0-46e4-8f98-137141cca49a'	System	18 Sep 2020 09:56:19
User entered 'Yes (Y)'	System	18 Sep 2020 09:56:19

FDA-CBER-2022-1614-3443601

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:01', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5949b6cf-efe0-46e4-8f98-137141cca49a'	System	18 Sep 2020 09:56:19
User entered '95.9'	System	18 Sep 2020 09:56:19

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:04', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5949b6cf-efe0-46e4-8f98-137141cca49a'	System	18 Sep 2020 09:56:19
User entered 'No (N)'	System	18 Sep 2020 09:56:19

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:11', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '5949b6cf-efe0-46e4-8f98-137141cca49a'	System	18 Sep 2020 09:56:19
User entered '18 Sep 2020 05:56'	System	18 Sep 2020 09:56:19

FDA-CBER-2022-1614-3443604

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '17 Sep 2020 14:15'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443605

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443606

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 2'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:27:53', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'c1938587-55a0-415a-bd19-6c9fc026ce36'	System	19 Sep 2020 01:28:08
User entered 'Yes (Y)'	System	19 Sep 2020 01:28:08

FDA-CBER-2022-1614-3443608

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:27:59', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'c1938587-55a0-415a-bd19-6c9fc026ce36'	System	19 Sep 2020 01:28:08
User entered '97.7'	System	19 Sep 2020 01:28:08

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:01', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'c1938587-55a0-415a-bd19-6c9fc026ce36'	System	19 Sep 2020 01:28:08
User entered 'No (N)'	System	19 Sep 2020 01:28:08

FDA-CBER-2022-1614-3443610

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:05', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'c1938587-55a0-415a-bd19-6c9fc026ce36'	System	19 Sep 2020 01:28:08
User entered '18 Sep 2020 21:28'	System	19 Sep 2020 01:28:08

FDA-CBER-2022-1614-3443611

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443612

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443613

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 3'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:16:41', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ae5e72bf-2257-4949-a186-ede13455d2b0'	System	20 Sep 2020 05:16:56
User entered 'Yes (Y)'	System	20 Sep 2020 05:16:56

FDA-CBER-2022-1614-3443615

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:16:46', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ae5e72bf-2257-4949-a186-ede13455d2b0'	System	20 Sep 2020 05:16:56
User entered '98.6'	System	20 Sep 2020 05:16:56

FDA-CBER-2022-1614-3443616

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:16:49', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ae5e72bf-2257-4949-a186-ede13455d2b0'	System	20 Sep 2020 05:16:56
User entered 'No (N)'	System	20 Sep 2020 05:16:56

FDA-CBER-2022-1614-3443617

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:16:51', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'ae5e72bf-2257-4949-a186-ede13455d2b0'	System	20 Sep 2020 05:16:56
User entered '20 Sep 2020 01:16'	System	20 Sep 2020 05:16:56

FDA-CBER-2022-1614-3443618

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443619

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443620

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 4'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:15:28', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69f8d027-1563-45fb-8ec3-935cca200235'	System	21 Sep 2020 02:15:47
User entered 'Yes (Y)'	System	21 Sep 2020 02:15:47

FDA-CBER-2022-1614-3443622

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:15:38', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69f8d027-1563-45fb-8ec3-935cca200235'	System	21 Sep 2020 02:15:47
User entered '98.8'	System	21 Sep 2020 02:15:47

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:15:41', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69f8d027-1563-45fb-8ec3-935cca200235'	System	21 Sep 2020 02:15:47
User entered 'No (N)'	System	21 Sep 2020 02:15:47

FDA-CBER-2022-1614-3443624

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:15:45', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69f8d027-1563-45fb-8ec3-935cca200235'	System	21 Sep 2020 02:15:47
User entered '20 Sep 2020 22:15'	System	21 Sep 2020 02:15:47

FDA-CBER-2022-1614-3443625

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443626

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443627

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 5'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:35', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '0411e940-de31-414b-b071-a408f45fe1e3'	System	21 Sep 2020 20:51:48
User entered 'Yes (Y)'	System	21 Sep 2020 20:51:48

FDA-CBER-2022-1614-3443629

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:39', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '0411e940-de31-414b-b071-a408f45fe1e3'	System	21 Sep 2020 20:51:48
User entered '95.9'	System	21 Sep 2020 20:51:48

FDA-CBER-2022-1614-3443630

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:42', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '0411e940-de31-414b-b071-a408f45fe1e3'	System	21 Sep 2020 20:51:48
User entered 'No (N)'	System	21 Sep 2020 20:51:48

FDA-CBER-2022-1614-3443631

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:44', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '0411e940-de31-414b-b071-a408f45fe1e3'	System	21 Sep 2020 20:51:48
User entered '21 Sep 2020 16:51'	System	21 Sep 2020 20:51:48

FDA-CBER-2022-1614-3443632

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443633

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443634

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 6'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:44:27', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a1f62094-e5c3-44c7-9e0e-0af29a147057'	System	23 Sep 2020 00:44:46
User entered 'Yes (Y)'	System	23 Sep 2020 00:44:46

FDA-CBER-2022-1614-3443636

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:44:33', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a1f62094-e5c3-44c7-9e0e-0af29a147057'	System	23 Sep 2020 00:44:46
User entered '97.3'	System	23 Sep 2020 00:44:46

FDA-CBER-2022-1614-3443637

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:44:39', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a1f62094-e5c3-44c7-9e0e-0af29a147057'	System	23 Sep 2020 00:44:46
User entered 'No (N)'	System	23 Sep 2020 00:44:46

FDA-CBER-2022-1614-3443638

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:44:43', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a1f62094-e5c3-44c7-9e0e-0af29a147057'	System	23 Sep 2020 00:44:46
User entered '22 Sep 2020 20:44'	System	23 Sep 2020 00:44:46

FDA-CBER-2022-1614-3443639

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443640

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443641

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 7'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:53', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8bcad1bf-8faf-4676-b6e1-49f5b037422c'	System	24 Sep 2020 06:33:24
User entered 'Yes (Y)'	System	24 Sep 2020 06:33:24

FDA-CBER-2022-1614-3443643

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:33:14', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8bcad1bf-8faf-4676-b6e1-49f5b037422c'	System	24 Sep 2020 06:33:24
User entered '95.6'	System	24 Sep 2020 06:33:24

FDA-CBER-2022-1614-3443644

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:33:18', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8bcad1bf-8faf-4676-b6e1-49f5b037422c'	System	24 Sep 2020 06:33:24
User entered 'No (N)'	System	24 Sep 2020 06:33:24

FDA-CBER-2022-1614-3443645

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:33:22', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8bcad1bf-8faf-4676-b6e1-49f5b037422c'	System	24 Sep 2020 06:33:24
User entered '24 Sep 2020 02:33'	System	24 Sep 2020 06:33:24

FDA-CBER-2022-1614-3443646

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443647

US3832237
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443648

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443649

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:09', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'c5de8b17-652d-47b1-9986-a4527a7f7e73'	System	17 Sep 2020 15:02:27
User entered 'None (1)'	System	17 Sep 2020 15:02:27

FDA-CBER-2022-1614-3443650

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:12', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'c5de8b17-652d-47b1-9986-a4527a7f7e73'	System	17 Sep 2020 15:02:27
User entered 'No (N)'	System	17 Sep 2020 15:02:27

FDA-CBER-2022-1614-3443651

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:15', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'c5de8b17-652d-47b1-9986-a4527a7f7e73'	System	17 Sep 2020 15:02:27
User entered 'No (N)'	System	17 Sep 2020 15:02:27

FDA-CBER-2022-1614-3443652

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:20', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'c5de8b17-652d-47b1-9986-a4527a7f7e73'	System	17 Sep 2020 15:02:27
User entered 'None (1)'	System	17 Sep 2020 15:02:27

FDA-CBER-2022-1614-3443653

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:25', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'c5de8b17-652d-47b1-9986-a4527a7f7e73'	System	17 Sep 2020 15:02:27
User entered '17 Sep 2020 11:02'	System	17 Sep 2020 15:02:27

FDA-CBER-2022-1614-3443654

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '17 Sep 2020 10:50'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443655

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '17 Sep 2020 13:20'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443656

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:18', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a0a6d76e-a2fa-4a90-aa9b-1a4871a74a4a'	System	18 Sep 2020 09:56:32
User entered 'None (1)'	System	18 Sep 2020 09:56:32

FDA-CBER-2022-1614-3443658

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:21', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a0a6d76e-a2fa-4a90-aa9b-1a4871a74a4a'	System	18 Sep 2020 09:56:32
User entered 'No (N)'	System	18 Sep 2020 09:56:32

FDA-CBER-2022-1614-3443659

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:23', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a0a6d76e-a2fa-4a90-aa9b-1a4871a74a4a'	System	18 Sep 2020 09:56:32
User entered 'No (N)'	System	18 Sep 2020 09:56:32

FDA-CBER-2022-1614-3443660

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:25', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a0a6d76e-a2fa-4a90-aa9b-1a4871a74a4a'	System	18 Sep 2020 09:56:32
User entered 'None (1)'	System	18 Sep 2020 09:56:32

FDA-CBER-2022-1614-3443661

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:28', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a0a6d76e-a2fa-4a90-aa9b-1a4871a74a4a'	System	18 Sep 2020 09:56:32
User entered '18 Sep 2020 05:56'	System	18 Sep 2020 09:56:32

FDA-CBER-2022-1614-3443662

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '17 Sep 2020 14:15'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443663

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443664

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 2'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:10', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '14131a1c-d988-438e-a5bf-585ff097de5e'	System	19 Sep 2020 01:28:27
User entered 'None (1)'	System	19 Sep 2020 01:28:27

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:13', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '14131a1c-d988-438e-a5bf-585ff097de5e'	System	19 Sep 2020 01:28:27
User entered 'No (N)'	System	19 Sep 2020 01:28:27

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:17', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '14131a1c-d988-438e-a5bf-585ff097de5e'	System	19 Sep 2020 01:28:27
User entered 'No (N)'	System	19 Sep 2020 01:28:27

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:20', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '14131a1c-d988-438e-a5bf-585ff097de5e'	System	19 Sep 2020 01:28:27
User entered 'None (1)'	System	19 Sep 2020 01:28:27

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US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:24', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '14131a1c-d988-438e-a5bf-585ff097de5e'	System	19 Sep 2020 01:28:27
User entered '18 Sep 2020 21:28'	System	19 Sep 2020 01:28:27

FDA-CBER-2022-1614-3443670

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

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US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

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US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 3'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:22', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd84b85e1-cbf6-42e6-8391-4f4f9d2fe684'	System	20 Sep 2020 05:13:39
User entered 'None (1)'	System	20 Sep 2020 05:13:39

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:25', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd84b85e1-cbf6-42e6-8391-4f4f9d2fe684'	System	20 Sep 2020 05:13:39
User entered 'No (N)'	System	20 Sep 2020 05:13:39

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:26', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd84b85e1-cbf6-42e6-8391-4f4f9d2fe684'	System	20 Sep 2020 05:13:39
User entered 'No (N)'	System	20 Sep 2020 05:13:39

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:28', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd84b85e1-cbf6-42e6-8391-4f4f9d2fe684'	System	20 Sep 2020 05:13:39
User entered 'None (1)'	System	20 Sep 2020 05:13:39

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:38', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd84b85e1-cbf6-42e6-8391-4f4f9d2fe684'	System	20 Sep 2020 05:13:39
User entered '20 Sep 2020 01:13'	System	20 Sep 2020 05:13:39

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

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US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

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US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 4'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443681

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:15:06', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'f2458cc5-75e3-4a13-9e1b-0548ac86df76'	System	21 Sep 2020 02:15:24
User entered 'None (1)'	System	21 Sep 2020 02:15:24

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US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:15:09', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'f2458cc5-75e3-4a13-9e1b-0548ac86df76'	System	21 Sep 2020 02:15:24
User entered 'No (N)'	System	21 Sep 2020 02:15:24

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:15:11', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'f2458cc5-75e3-4a13-9e1b-0548ac86df76'	System	21 Sep 2020 02:15:24
User entered 'No (N)'	System	21 Sep 2020 02:15:24

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:15:13', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'f2458cc5-75e3-4a13-9e1b-0548ac86df76'	System	21 Sep 2020 02:15:24
User entered 'None (1)'	System	21 Sep 2020 02:15:24

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US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:15:22', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'f2458cc5-75e3-4a13-9e1b-0548ac86df76'	System	21 Sep 2020 02:15:24
User entered '20 Sep 2020 22:15'	System	21 Sep 2020 02:15:24

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US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443687

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

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US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 5'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:48', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd5bbdc4e-e793-4a19-b935-8200eea2d2e5'	System	21 Sep 2020 20:52:05
User entered 'None (1)'	System	21 Sep 2020 20:52:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:52', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd5bbdc4e-e793-4a19-b935-8200eea2d2e5'	System	21 Sep 2020 20:52:05
User entered 'No (N)'	System	21 Sep 2020 20:52:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:55', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd5bbdc4e-e793-4a19-b935-8200eea2d2e5'	System	21 Sep 2020 20:52:05
User entered 'No (N)'	System	21 Sep 2020 20:52:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:57', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd5bbdc4e-e793-4a19-b935-8200eea2d2e5'	System	21 Sep 2020 20:52:05
User entered 'None (1)'	System	21 Sep 2020 20:52:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:52:00', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd5bbdc4e-e793-4a19-b935-8200eea2d2e5'	System	21 Sep 2020 20:52:05
User entered '21 Sep 2020 16:52'	System	21 Sep 2020 20:52:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

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US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 6'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:44:48', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '843e2961-9e5a-4cdb-bd0c-e4790966a936'	System	23 Sep 2020 00:45:06
User entered 'None (1)'	System	23 Sep 2020 00:45:06

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:44:51', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '843e2961-9e5a-4cdb-bd0c-e4790966a936'	System	23 Sep 2020 00:45:06
User entered 'No (N)'	System	23 Sep 2020 00:45:06

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:44:54', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '843e2961-9e5a-4cdb-bd0c-e4790966a936'	System	23 Sep 2020 00:45:06
User entered 'No (N)'	System	23 Sep 2020 00:45:06

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:44:57', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '843e2961-9e5a-4cdb-bd0c-e4790966a936'	System	23 Sep 2020 00:45:06
User entered 'None (1)'	System	23 Sep 2020 00:45:06

FDA-CBER-2022-1614-3443701

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:45:01', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '843e2961-9e5a-4cdb-bd0c-e4790966a936'	System	23 Sep 2020 00:45:06
User entered '22 Sep 2020 20:45'	System	23 Sep 2020 00:45:06

FDA-CBER-2022-1614-3443702

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443703

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443704

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 7'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:06', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a1d30124-b8d7-485e-b082-22bea246fefb'	System	24 Sep 2020 06:32:21
User entered 'None (1)'	System	24 Sep 2020 06:32:21

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:08', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a1d30124-b8d7-485e-b082-22bea246fefb'	System	24 Sep 2020 06:32:21
User entered 'No (N)'	System	24 Sep 2020 06:32:21

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:10', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a1d30124-b8d7-485e-b082-22bea246fefb'	System	24 Sep 2020 06:32:21
User entered 'No (N)'	System	24 Sep 2020 06:32:21

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:14', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a1d30124-b8d7-485e-b082-22bea246fefb'	System	24 Sep 2020 06:32:21
User entered 'None (1)'	System	24 Sep 2020 06:32:21

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:18', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'a1d30124-b8d7-485e-b082-22bea246fefb'	System	24 Sep 2020 06:32:21
User entered '24 Sep 2020 02:32'	System	24 Sep 2020 06:32:21

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443712

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443713

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:34', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '1059beb1-6951-45aa-97a6-0ca046f89036'	System	17 Sep 2020 15:02:59
User entered 'None (0)'	System	17 Sep 2020 15:02:59

FDA-CBER-2022-1614-3443714

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:37', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '1059beb1-6951-45aa-97a6-0ca046f89036'	System	17 Sep 2020 15:02:59
User entered 'None (0)'	System	17 Sep 2020 15:02:59

FDA-CBER-2022-1614-3443715

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:41', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '1059beb1-6951-45aa-97a6-0ca046f89036'	System	17 Sep 2020 15:02:59
User entered 'None (0)'	System	17 Sep 2020 15:02:59

FDA-CBER-2022-1614-3443716

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:44', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '1059beb1-6951-45aa-97a6-0ca046f89036'	System	17 Sep 2020 15:02:59
User entered 'None (0)'	System	17 Sep 2020 15:02:59

FDA-CBER-2022-1614-3443717

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:46', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '1059beb1-6951-45aa-97a6-0ca046f89036'	System	17 Sep 2020 15:02:59
User entered 'None (0)'	System	17 Sep 2020 15:02:59

FDA-CBER-2022-1614-3443718

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:48', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '1059beb1-6951-45aa-97a6-0ca046f89036'	System	17 Sep 2020 15:02:59
User entered 'None (0)'	System	17 Sep 2020 15:02:59

FDA-CBER-2022-1614-3443719

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:51', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '1059beb1-6951-45aa-97a6-0ca046f89036'	System	17 Sep 2020 15:02:59
User entered 'No (N)'	System	17 Sep 2020 15:02:59

FDA-CBER-2022-1614-3443720

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-17T11:02:55', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '1059beb1-6951-45aa-97a6-0ca046f89036'	System	17 Sep 2020 15:02:59
User entered '17 Sep 2020 11:02'	System	17 Sep 2020 15:02:59

FDA-CBER-2022-1614-3443721

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '17 Sep 2020 10:50'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443722

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '17 Sep 2020 13:20'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:31', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69b84113-84f8-4229-81cd-a7e659db2bed'	System	18 Sep 2020 09:56:47
User entered 'None (0)'	System	18 Sep 2020 09:56:47

FDA-CBER-2022-1614-3443725

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:33', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69b84113-84f8-4229-81cd-a7e659db2bed'	System	18 Sep 2020 09:56:47
User entered 'None (0)'	System	18 Sep 2020 09:56:47

FDA-CBER-2022-1614-3443726

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:35', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69b84113-84f8-4229-81cd-a7e659db2bed'	System	18 Sep 2020 09:56:47
User entered 'None (0)'	System	18 Sep 2020 09:56:47

FDA-CBER-2022-1614-3443727

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:36', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69b84113-84f8-4229-81cd-a7e659db2bed'	System	18 Sep 2020 09:56:47
User entered 'None (0)'	System	18 Sep 2020 09:56:47

FDA-CBER-2022-1614-3443728

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:38', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69b84113-84f8-4229-81cd-a7e659db2bed'	System	18 Sep 2020 09:56:47
User entered 'None (0)'	System	18 Sep 2020 09:56:47

FDA-CBER-2022-1614-3443729

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:40', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69b84113-84f8-4229-81cd-a7e659db2bed'	System	18 Sep 2020 09:56:47
User entered 'None (0)'	System	18 Sep 2020 09:56:47

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:41', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69b84113-84f8-4229-81cd-a7e659db2bed'	System	18 Sep 2020 09:56:47
User entered 'No (N)'	System	18 Sep 2020 09:56:47

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T05:56:44', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '69b84113-84f8-4229-81cd-a7e659db2bed'	System	18 Sep 2020 09:56:47
User entered '18 Sep 2020 05:56'	System	18 Sep 2020 09:56:47

FDA-CBER-2022-1614-3443732

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '17 Sep 2020 14:15'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443733

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443734

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 2'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:30', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd7986d8f-a7e4-4a53-a66a-66282fa2bac6'	System	19 Sep 2020 01:28:52
User entered 'None (0)'	System	19 Sep 2020 01:28:52

FDA-CBER-2022-1614-3443736

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:32', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd7986d8f-a7e4-4a53-a66a-66282fa2bac6'	System	19 Sep 2020 01:28:52
User entered 'None (0)'	System	19 Sep 2020 01:28:52

FDA-CBER-2022-1614-3443737

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:34', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd7986d8f-a7e4-4a53-a66a-66282fa2bac6'	System	19 Sep 2020 01:28:52
User entered 'None (0)'	System	19 Sep 2020 01:28:52

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:37', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd7986d8f-a7e4-4a53-a66a-66282fa2bac6'	System	19 Sep 2020 01:28:52
User entered 'None (0)'	System	19 Sep 2020 01:28:52

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:39', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd7986d8f-a7e4-4a53-a66a-66282fa2bac6'	System	19 Sep 2020 01:28:52
User entered 'None (0)'	System	19 Sep 2020 01:28:52

FDA-CBER-2022-1614-3443740

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:41', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd7986d8f-a7e4-4a53-a66a-66282fa2bac6'	System	19 Sep 2020 01:28:52
User entered 'None (0)'	System	19 Sep 2020 01:28:52

FDA-CBER-2022-1614-3443741

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:47', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd7986d8f-a7e4-4a53-a66a-66282fa2bac6'	System	19 Sep 2020 01:28:52
User entered 'No (N)'	System	19 Sep 2020 01:28:52

FDA-CBER-2022-1614-3443742

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-18T21:28:50', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'd7986d8f-a7e4-4a53-a66a-66282fa2bac6'	System	19 Sep 2020 01:28:52
User entered '18 Sep 2020 21:28'	System	19 Sep 2020 01:28:52

FDA-CBER-2022-1614-3443743

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443744

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443745

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 3'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:04', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '01f460be-af1b-4afc-a005-c5801547bdef'	System	20 Sep 2020 05:13:22
User entered 'None (0)'	System	20 Sep 2020 05:13:22

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:05', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '01f460be-af1b-4afc-a005-c5801547bdef'	System	20 Sep 2020 05:13:22
User entered 'None (0)'	System	20 Sep 2020 05:13:22

FDA-CBER-2022-1614-3443748

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:08', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '01f460be-af1b-4afc-a005-c5801547bdef'	System	20 Sep 2020 05:13:22
User entered 'None (0)'	System	20 Sep 2020 05:13:22

FDA-CBER-2022-1614-3443749

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:10', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '01f460be-af1b-4afc-a005-c5801547bdef'	System	20 Sep 2020 05:13:22
User entered 'None (0)'	System	20 Sep 2020 05:13:22

FDA-CBER-2022-1614-3443750

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:11', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '01f460be-af1b-4afc-a005-c5801547bdef'	System	20 Sep 2020 05:13:22
User entered 'None (0)'	System	20 Sep 2020 05:13:22

FDA-CBER-2022-1614-3443751

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:13', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '01f460be-af1b-4afc-a005-c5801547bdef'	System	20 Sep 2020 05:13:22
User entered 'None (0)'	System	20 Sep 2020 05:13:22

FDA-CBER-2022-1614-3443752

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:15', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '01f460be-af1b-4afc-a005-c5801547bdef'	System	20 Sep 2020 05:13:22
User entered 'No (N)'	System	20 Sep 2020 05:13:22

FDA-CBER-2022-1614-3443753

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T01:13:18', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '01f460be-af1b-4afc-a005-c5801547bdef'	System	20 Sep 2020 05:13:22
User entered '20 Sep 2020 01:13'	System	20 Sep 2020 05:13:22

FDA-CBER-2022-1614-3443754

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443755

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443756

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 4'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:14:49', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '422c9200-74bc-4687-b1f2-218762b39743'	System	21 Sep 2020 02:15:07
User entered 'None (0)'	System	21 Sep 2020 02:15:07

FDA-CBER-2022-1614-3443758

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:14:50', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '422c9200-74bc-4687-b1f2-218762b39743'	System	21 Sep 2020 02:15:07
User entered 'None (0)'	System	21 Sep 2020 02:15:07

FDA-CBER-2022-1614-3443759

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:14:52', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '422c9200-74bc-4687-b1f2-218762b39743'	System	21 Sep 2020 02:15:07
User entered 'None (0)'	System	21 Sep 2020 02:15:07

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:14:53', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '422c9200-74bc-4687-b1f2-218762b39743'	System	21 Sep 2020 02:15:07
User entered 'None (0)'	System	21 Sep 2020 02:15:07

FDA-CBER-2022-1614-3443761

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:14:55', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '422c9200-74bc-4687-b1f2-218762b39743'	System	21 Sep 2020 02:15:07
User entered 'None (0)'	System	21 Sep 2020 02:15:07

FDA-CBER-2022-1614-3443762

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:14:57', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '422c9200-74bc-4687-b1f2-218762b39743'	System	21 Sep 2020 02:15:07
User entered 'None (0)'	System	21 Sep 2020 02:15:07

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:14:59', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '422c9200-74bc-4687-b1f2-218762b39743'	System	21 Sep 2020 02:15:07
User entered 'No (N)'	System	21 Sep 2020 02:15:07

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-20T22:15:03', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '422c9200-74bc-4687-b1f2-218762b39743'	System	21 Sep 2020 02:15:07
User entered '20 Sep 2020 22:15'	System	21 Sep 2020 02:15:07

FDA-CBER-2022-1614-3443765

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 5'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:50:52', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '15e39707-94b5-4ef1-b8c9-3100b66b41cb'	System	21 Sep 2020 20:51:31
User entered 'None (0)'	System	21 Sep 2020 20:51:31

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:01', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '15e39707-94b5-4ef1-b8c9-3100b66b41cb'	System	21 Sep 2020 20:51:31
User entered 'None (0)'	System	21 Sep 2020 20:51:31

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:08', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '15e39707-94b5-4ef1-b8c9-3100b66b41cb'	System	21 Sep 2020 20:51:31
User entered 'None (0)'	System	21 Sep 2020 20:51:31

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US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:09', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '15e39707-94b5-4ef1-b8c9-3100b66b41cb'	System	21 Sep 2020 20:51:31
User entered 'None (0)'	System	21 Sep 2020 20:51:31

FDA-CBER-2022-1614-3443772

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:11', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '15e39707-94b5-4ef1-b8c9-3100b66b41cb'	System	21 Sep 2020 20:51:31
User entered 'None (0)'	System	21 Sep 2020 20:51:31

FDA-CBER-2022-1614-3443773

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:13', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '15e39707-94b5-4ef1-b8c9-3100b66b41cb'	System	21 Sep 2020 20:51:31
User entered 'None (0)'	System	21 Sep 2020 20:51:31

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:16', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '15e39707-94b5-4ef1-b8c9-3100b66b41cb'	System	21 Sep 2020 20:51:31
User entered 'No (N)'	System	21 Sep 2020 20:51:31

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-21T16:51:29', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '15e39707-94b5-4ef1-b8c9-3100b66b41cb'	System	21 Sep 2020 20:51:31
User entered '21 Sep 2020 16:51'	System	21 Sep 2020 20:51:31

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 6'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:45:06', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8b4346e8-8a4e-4f17-8eb9-fed04e37d358'	System	23 Sep 2020 00:45:31
User entered 'None (0)'	System	23 Sep 2020 00:45:31

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US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:45:08', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8b4346e8-8a4e-4f17-8eb9-fed04e37d358'	System	23 Sep 2020 00:45:31
User entered 'None (0)'	System	23 Sep 2020 00:45:31

FDA-CBER-2022-1614-3443781

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:45:11', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8b4346e8-8a4e-4f17-8eb9-fed04e37d358'	System	23 Sep 2020 00:45:31
User entered 'None (0)'	System	23 Sep 2020 00:45:31

FDA-CBER-2022-1614-3443782

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:45:16', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8b4346e8-8a4e-4f17-8eb9-fed04e37d358'	System	23 Sep 2020 00:45:31
User entered 'None (0)'	System	23 Sep 2020 00:45:31

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:45:19', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8b4346e8-8a4e-4f17-8eb9-fed04e37d358'	System	23 Sep 2020 00:45:31
User entered 'None (0)'	System	23 Sep 2020 00:45:31

FDA-CBER-2022-1614-3443784

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:45:22', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8b4346e8-8a4e-4f17-8eb9-fed04e37d358'	System	23 Sep 2020 00:45:31
User entered 'None (0)'	System	23 Sep 2020 00:45:31

FDA-CBER-2022-1614-3443785

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:45:25', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8b4346e8-8a4e-4f17-8eb9-fed04e37d358'	System	23 Sep 2020 00:45:31
User entered 'No (N)'	System	23 Sep 2020 00:45:31

FDA-CBER-2022-1614-3443786

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-22T20:45:28', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '8b4346e8-8a4e-4f17-8eb9-fed04e37d358'	System	23 Sep 2020 00:45:31
User entered '22 Sep 2020 20:45'	System	23 Sep 2020 00:45:31

FDA-CBER-2022-1614-3443787

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

FDA-CBER-2022-1614-3443788

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	17 Sep 2020 14:45:05
User entered 'Day 7'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:23', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2d66a648-29ab-4559-8114-5ca8d96d443d'	System	24 Sep 2020 06:32:47
User entered 'None (0)'	System	24 Sep 2020 06:32:47

FDA-CBER-2022-1614-3443791

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:26', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2d66a648-29ab-4559-8114-5ca8d96d443d'	System	24 Sep 2020 06:32:47
User entered 'None (0)'	System	24 Sep 2020 06:32:47

FDA-CBER-2022-1614-3443792

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:28', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2d66a648-29ab-4559-8114-5ca8d96d443d'	System	24 Sep 2020 06:32:47
User entered 'None (0)'	System	24 Sep 2020 06:32:47

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:32', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2d66a648-29ab-4559-8114-5ca8d96d443d'	System	24 Sep 2020 06:32:47
User entered 'None (0)'	System	24 Sep 2020 06:32:47

FDA-CBER-2022-1614-3443794

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:34', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2d66a648-29ab-4559-8114-5ca8d96d443d'	System	24 Sep 2020 06:32:47
User entered 'None (0)'	System	24 Sep 2020 06:32:47

FDA-CBER-2022-1614-3443795

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:36', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2d66a648-29ab-4559-8114-5ca8d96d443d'	System	24 Sep 2020 06:32:47
User entered 'None (0)'	System	24 Sep 2020 06:32:47

FDA-CBER-2022-1614-3443796

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:40', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2d66a648-29ab-4559-8114-5ca8d96d443d'	System	24 Sep 2020 06:32:47
User entered 'No (N)'	System	24 Sep 2020 06:32:47

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US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-09-24T02:32:43', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2d66a648-29ab-4559-8114-5ca8d96d443d'	System	24 Sep 2020 06:32:47
User entered '24 Sep 2020 02:32'	System	24 Sep 2020 06:32:47

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:45:05

US3832237
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:01:21
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:45:05

US3832237
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	05 Oct 2020 13:23:05

US3832237
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '24 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	05 Oct 2020 13:23:05

US3832237
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	05 Oct 2020 13:23:05

US3832237
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Oct 2020 13:23:05

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US3832237
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	05 Oct 2020 13:23:12

US3832237
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	05 Oct 2020 13:23:12

US3832237
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	08 Oct 2020 15:04:18

US3832237
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '01 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	08 Oct 2020 15:04:18

US3832237
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	08 Oct 2020 15:04:18

US3832237
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	08 Oct 2020 15:04:18

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US3832237
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	08 Oct 2020 15:04:25

US3832237
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	08 Oct 2020 15:04:25

FDA-CBER-2022-1614-3443812

US3832237
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	08 Oct 2020 15:04:53

US3832237
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '08 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	08 Oct 2020 15:04:53

US3832237
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	08 Oct 2020 15:04:53

US3832237
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	08 Oct 2020 15:04:53

US3832237
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	08 Oct 2020 15:05:00

US3832237
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	08 Oct 2020 15:05:00

US3832237
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:44:09

US3832237
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Date of Visit is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Visit is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '15 Oct 2020'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:44:09

US3832237
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Clinic (Clinic)'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:44:09

US3832237
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:01:21
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'VISIT3'	System	15 Oct 2020 14:44:09

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US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:45:33

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Assessment is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '15 Oct 2020'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:45:33

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '10:25'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:45:33

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '15 Oct 2020 10:25'	System	15 Oct 2020 14:45:33

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '98.2' F	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:45:33

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Oral (Oral)'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:45:33

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered empty.	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:45:33

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '74'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:45:33

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'bpm'	System	15 Oct 2020 14:45:33

FDA-CBER-2022-1614-3443831

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '14'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:45:33

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'breaths/min'	System	15 Oct 2020 14:45:33

FDA-CBER-2022-1614-3443833

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '131'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:45:33

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	15 Oct 2020 14:45:33

FDA-CBER-2022-1614-3443835

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '93'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:45:33

FDA-CBER-2022-1614-3443836

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered 'mmHg'	System	15 Oct 2020 14:45:33

FDA-CBER-2022-1614-3443837

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59

FDA-CBER-2022-1614-3443838

US3832237
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:01:21
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59

FDA-CBER-2022-1614-3443839

US3832237
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:01:21
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:46:03

US3832237
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:01:21
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Physical Examination Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User closed query 'Physical Examination is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Physical Examination Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User opened query 'Physical Examination is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '15 Oct 2020'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:46:03

US3832237
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:46:22

US3832237
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User closed query 'Collection date is after date of death. Please update as appropriate.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Collection date is after date of death. Please update as appropriate.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '15 Oct 2020'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:46:22

US3832237
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered '10:35'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:46:22

US3832237
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:01:21
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '15 Oct 2020 10:35'	System	15 Oct 2020 14:46:22

US3832237
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:27:21
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	15 Oct 2020 14:46:48

US3832237
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	15 Oct 2020 14:46:48

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US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 64'	System	20 Aug 2020 16:01:11

US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-10-22T08:28:57', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '21755ca2-5d53-424f-a4ad-8395c7a2ff7d'	System	22 Oct 2020 12:29:14
User entered 'No (N)'	System	22 Oct 2020 12:29:14

US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-10-22T08:29:03', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '21755ca2-5d53-424f-a4ad-8395c7a2ff7d'	System	22 Oct 2020 12:29:14
User entered 'No (N)'	System	22 Oct 2020 12:29:14

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-10-22T08:29:12', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '21755ca2-5d53-424f-a4ad-8395c7a2ff7d'	System	22 Oct 2020 12:29:14
User entered '22 Oct 2020 08:29:12'	System	22 Oct 2020 12:29:14

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 16:01:11

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 16:01:11

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 71'	System	20 Aug 2020 16:01:11

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US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-10-29T08:46:54', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2dba0241-67a9-4ac6-ba88-a4dd2ab56630'	System	29 Oct 2020 12:47:08
User entered 'No (N)'	System	29 Oct 2020 12:47:08

US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-10-29T08:47:00', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2dba0241-67a9-4ac6-ba88-a4dd2ab56630'	System	29 Oct 2020 12:47:08
User entered 'No (N)'	System	29 Oct 2020 12:47:08

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-10-29T08:47:05', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: '2dba0241-67a9-4ac6-ba88-a4dd2ab56630'	System	29 Oct 2020 12:47:08
User entered '29 Oct 2020 08:47:05'	System	29 Oct 2020 12:47:08

FDA-CBER-2022-1614-3443857

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 16:01:11

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 16:01:11

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 78'	System	20 Aug 2020 16:01:11

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US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-11-05T22:09:56', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'b7b20c8b-9e8b-47a4-84dd-8fbb6840eab6'	System	06 Nov 2020 03:10:07
User entered 'No (N)'	System	06 Nov 2020 03:10:07

US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-11-05T22:10:01', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'b7b20c8b-9e8b-47a4-84dd-8fbb6840eab6'	System	06 Nov 2020 03:10:07
User entered 'No (N)'	System	06 Nov 2020 03:10:07

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D622518A-4BCA-4793-A068-FC95BA7A9ECB)', Time: '2020-11-05T22:10:05', User OID: 'PatientReportedOutcome (US3832237)', ODM File OID: 'b7b20c8b-9e8b-47a4-84dd-8fbb6840eab6'	System	06 Nov 2020 03:10:07
User entered '05 Nov 2020 22:10:05'	System	06 Nov 2020 03:10:07

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 16:01:11

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:38:09
Data entry locked.	System	20 Aug 2020 16:01:11
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 16:01:11

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17
Data entry locked.	System	20 Aug 2020 16:01:11
User entered 'Day 92'	System	20 Aug 2020 16:01:11

US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17
Data entry locked.	System	20 Aug 2020 16:01:11
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 16:01:11

US3832237
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:01:21
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:42:17
Data entry locked.	System	20 Aug 2020 16:01:11
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 16:01:11

US3832237
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User closed query 'The last EDC entry was 12 Nov 2020. Please update all visits in the EDC.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 17:55:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
Query 'The last EDC entry was 12 Nov 2020. Please update all visits in the EDC.' answered with 'Day 85 updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 19:39:13
User opened query 'The last EDC entry was 12 Nov 2020. Please update all visits in the EDC.' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 14:51:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Nov 2020 15:00:58

US3832237
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '12 Nov 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Nov 2020 15:00:58

FDA-CBER-2022-1614-3443895

US3832237
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Nov 2020 15:00:58

US3832237
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:01:21
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Nov 2020 15:00:58

FDA-CBER-2022-1614-3443897

US3832237
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 19:38:19
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Nov 2020 15:01:03

US3832237
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:01:21
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	09 Feb 2021 19:38:19
User entered '1'	System	12 Nov 2020 15:01:03

US3832237
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 10:01:21
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:11:48
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:22

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59

FDA-CBER-2022-1614-3443901

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 15:05:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 15:05:23
Data point term sent to Coder	System	15 Oct 2020 14:32:16
User entered 'Worsening of Hypertension'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '08 Oct 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:56:40
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'End date is after date of death. Please update as appropriate.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'End date is after date of death. Please update as appropriate.' (Site from System).	System	03 Feb 2021 14:16:47
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Oct 2020 14:56:49
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	15 Oct 2020 14:56:49
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Oct 2020 14:56:40
User entered '15 Oct 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:56:40
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
User closed query 'Per CDM Re-query: Site has recorded 'AE Severity' of AE Log Line 1, initially as 'Grade 1/Mild', then changed it to 'Grade 2/Moderate', then changed it back again to 'Grade 1/Mild'. Please note, 'Hypertension' is recorded in Medical History, and AE Log Line 1 represents a 'Worsening of Hypertension'. In alignment with page 45 of v4.0 of CCGs, “Changes in the severity of an AE should be documented in the participant’s source documentation to allow an assessment of the duration of the event at each level of intensity to be performed. An AE characterized as intermittent requires documentation of onset and duration of each episode. An AE that fluctuates in severity during the course of the event is reported once in the eCRF at the highest severity observed. Per page 45 of CCGs: "Grade 1/Mild: These events do not interfere with the participant’s daily activities. Grade 2/Moderate: These events cause some interference with the participant’s daily activities but do not require limited medical intervention. Grade 3/Severe: These events prevent the participant’s daily activity and require intensive therapeutic intervention. Grade 4: These events require an emergency room visit or hospitalization.” Therefore, in order to satisfy previous query, please verify data and if appropriate, update AE Severity field and reconcile with all applicable forms, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:29:05

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Severity

Audit	User	Time (GMT)
Query 'Per CDM Re-query: Site has recorded 'AE Severity' of AE Log Line 1, initially as 'Grade 1/Mild', then changed it to 'Grade 2/Moderate', then changed it back again to 'Grade 1/Mild'. Please note, 'Hypertension' is recorded in Medical History, and AE Log Line 1 represents a 'Worsening of Hypertension'. In alignment with page 45 of v4.0 of CCGs, “Changes in the severity of an AE should be documented in the participant’s source documentation to allow an assessment of the duration of the event at each level of intensity to be performed. An AE characterized as intermittent requires documentation of onset and duration of each episode. An AE that fluctuates in severity during the course of the event is reported once in the eCRF at the highest severity observed. Per page 45 of CCGs: "Grade 1/Mild: These events do not interfere with the participant’s daily activities. Grade 2/Moderate: These events cause some interference with the participant’s daily activities but do not require limited medical intervention. Grade 3/Severe: These events prevent the participant’s daily activity and require intensive therapeutic intervention. Grade 4: These events require an emergency room visit or hospitalization.” Therefore, in order to satisfy previous query, please verify data and if appropriate, update AE Severity field and reconcile with all applicable forms, else clarify. Thank you.' answered with 'Noted as a Grade 1/Mild as this event did not interfere with the participant’s daily activities' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	26 Jan 2021 21:20:46

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Severity

Audit	User	Time (GMT)
User opened query 'Per CDM Re-query: Site has recorded 'AE Severity' of AE Log Line 1, initially as 'Grade 1/Mild', then changed it to 'Grade 2/Moderate', then changed it back again to 'Grade 1/Mild'. Please note, 'Hypertension' is recorded in Medical History, and AE Log Line 1 represents a 'Worsening of Hypertension'. In alignment with page 45 of v4.0 of CCGs, “Changes in the severity of an AE should be documented in the participant’s source documentation to allow an assessment of the duration of the event at each level of intensity to be performed. An AE characterized as intermittent requires documentation of onset and duration of each episode. An AE that fluctuates in severity during the course of the event is reported once in the eCRF at the highest severity observed. Per page 45 of CCGs: "Grade 1/Mild: These events do not interfere with the participant’s daily activities. Grade 2/Moderate: These events cause some interference with the participant’s daily activities but do not require limited medical intervention. Grade 3/Severe: These events prevent the participant’s daily activity and require intensive therapeutic intervention. Grade 4: These events require an emergency room visit or hospitalization.” Therefore, in order to satisfy previous query, please verify data and if appropriate, update AE Severity field and reconcile with all applicable forms, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 17:15:43
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:09:29
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 13:15:03

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Severity

Audit	User	Time (GMT)
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' answered with 'updated ' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	11 Nov 2020 16:38:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	11 Nov 2020 16:36:44
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 09:58:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

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US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Not Applicable (NOT APPLICABLE)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '1'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	11 Nov 2020 16:37:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:56:49
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 14:31:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 14:31:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:34
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 14:31:21
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Per CDM: Kindly update this 'If outcome is Recovered/Resolved with Sequelae, please specify the Sequelae' field to provide extra clarity, since subject was taking more than one medication for 'Hypertension'. If subject reported that the increased Losartan medication dosage (from 50mg once daily to 100mg once daily) which started on 08Oct2020 helped with 'Worsening of Hypertension', please include those details on this field. AE End-Date for 'Worsening of Hypertension' is recorded as 15Oct2020, however, on Log Line 8 of ConMed form, the increased dosage of 100mg once daily of Losartan is recorded as ongoing. Please verify data and reconcile with all appropriate forms per Protocol. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:43:08
Query 'Per CDM: Kindly update this 'If outcome is Recovered/Resolved with Sequelae, please specify the Sequelae' field to provide extra clarity, since subject was taking more than one medication for 'Hypertension'. If subject reported that the increased Losartan medication dosage (from 50mg once daily to 100mg once daily) which started on 08Oct2020 helped with 'Worsening of Hypertension', please include those details on this field. AE End-Date for 'Worsening of Hypertension' is recorded as 15Oct2020, however, on Log Line 8 of ConMed form, the increased dosage of 100mg once daily of Losartan is recorded as ongoing. Please verify data and reconcile with all appropriate forms per Protocol. Thank you.' answered with 'Updated per query' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	26 Jan 2021 21:23:30
User entered 'Increase in Losartan medication dosage (from 50mg once daily to 100mg once daily) which started on 08Oct2020 helped with 'Worsening of Hypertension',' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	26 Jan 2021 21:23:21

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US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User opened query 'Per CDM: Kindly update this 'If outcome is Recovered/Resolved with Sequelae, please specify the Sequelae' field to provide extra clarity, since subject was taking more than one medication for 'Hypertension'. If subject reported that the increased Losartan medication dosage (from 50mg once daily to 100mg once daily) which started on 08Oct2020 helped with 'Worsening of Hypertension', please include those details on this field. AE End-Date for 'Worsening of Hypertension' is recorded as 15Oct2020, however, on Log Line 8 of ConMed form, the increased dosage of 100mg once daily of Losartan is recorded as ongoing. Please verify data and reconcile with all appropriate forms per Protocol. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 16:48:45
Query 'Per CDM: Kindly update this 'If outcome is Recovered/Resolved with Sequelae, please specify the Sequelae' field to provide extra clarity, since subject was taking more than one medication for Hypertension. If subject reported that the increased Losartan medication dosage (from 50mg once daily to 100mg once daily) which started on 08Oct2020 helped with 'Worsening of Hypertension', please include those details on this field. AE End-Date for 'Worsening of Hypertension' is recorded as 15Oct2020, however, on Log Line 8 of ConMed form, the increased dosage of 100mg once daily of Losartan is recorded as ongoing. Please verify data and reconcile with all appropriate forms per Protocol. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 16:48:29

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User opened query 'Per CDM: Kindly update this 'If outcome is Recovered/Resolved with Sequelae, please specify the Sequelae' field to provide extra clarity, since subject was taking more than one medication for Hypertension. If subject reported that the increased Losartan medication dosage (from 50mg once daily to 100mg once daily) which started on 08Oct2020 helped with 'Worsening of Hypertension', please include those details on this field. AE End-Date for 'Worsening of Hypertension' is recorded as 15Oct2020, however, on Log Line 8 of ConMed form, the increased dosage of 100mg once daily of Losartan is recorded as ongoing. Please verify data and reconcile with all appropriate forms per Protocol. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 16:48:21
Query 'Per CDM: Kindly update this 'If outcome is Recovered/Resolved with Sequelae, please specify the Sequelae' field to provide extra clarity, since subject was taking more than one medication for Hypertension. If subject reported that the increased Losartan medication dosage (from 50mg once daily to 100mg once daily) which started on 08Oct2020 helped with hypertension, please include those details on this field. The AE End-Date for 'Worsening of Hypertension' is recorded as 15Oct2020, however, on Log Line 8 of ConMed form, the increased dosage of 100mg once daily of Losartan is recorded as ongoing. Please verify data and reconcile with all appropriate forms per Protocol. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 16:46:47

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User opened query 'Per CDM: Kindly update this 'If outcome is Recovered/Resolved with Sequelae, please specify the Sequelae' field to provide extra clarity, since subject was taking more than one medication for Hypertension. If subject reported that the increased Losartan medication dosage (from 50mg once daily to 100mg once daily) which started on 08Oct2020 helped with hypertension, please include those details on this field. The AE End-Date for 'Worsening of Hypertension' is recorded as 15Oct2020, however, on Log Line 8 of ConMed form, the increased dosage of 100mg once daily of Losartan is recorded as ongoing. Please verify data and reconcile with all appropriate forms per Protocol. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 16:45:49
Query 'Per CDM: Please update this 'Specify the sequelae' field to provide extra clarity, as subject was taking more than one medication for Hypertension. Did subject report that increasing Losartan medication dosage (from 50mg once daily to 100mg once daily) and staying on this increased dose of Losartan from 08Oct onwards, has helped with Hypertension? If so, please update data as appropriate. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 16:35:30
User opened query 'Per CDM: Please update this 'Specify the sequelae' field to provide extra clarity, as subject was taking more than one medication for Hypertension. Did subject report that increasing Losartan medication dosage (from 50mg once daily to 100mg once daily) and staying on this increased dose of Losartan from 08Oct onwards, has helped with Hypertension? If so, please update data as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 16:34:18
User entered 'Subject reports that increased medication has helped with hypertension. Subject continues on current dose of losartan' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	11 Nov 2020 16:37:54
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '0'	System	15 Oct 2020 14:31:21

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US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	15 Oct 2020 14:31:21

US3832237
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:01:21
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59

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US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 20:49:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:25
User entered 'USA-US100-2020-mRNA-1273-P301000008'	System	02 Dec 2020 18:03:19
User entered 'New'	(b) (4), (b) (6)	02 Dec 2020 18:03:19

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User closed query 'please confirm if death certificate is available yet.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 17:53:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
Query 'please confirm if death certificate is available yet.' answered with 'Death certificate unavailable ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	19 Feb 2021 18:01:49
User opened query 'please confirm if death certificate is available yet.' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 01:20:05
User closed query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death. If the information will not be available at anytime in the future, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 14:32:22
User closed query 'Per CDM: Please verify data and update End of Study/ Study Discontinuation form as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 08:54:16
Query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death. If the information will not be available at anytime in the future, please state so in your response.' answered with 'The information will not be available in the foreseeable future' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 14:15:40
Query 'Per CDM: Please verify data and update End of Study/ Study Discontinuation form as appropriate. Thank you.' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 14:15:17
User opened query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death. If the information will not be available at anytime in the future, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:17:51
User opened query 'Per CDM: Please verify data and update End of Study/ Study Discontinuation form as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 21:21:07

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Adverse event

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 12:44:26
Query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' answered with 'Cause is unknown site is unable to obtain any additional information at this time' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	19 Jan 2021 23:06:40
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:49:54
User opened query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:34:39
User closed query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:26:34
Query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' answered with 'Its currently unknown' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:04:12
User opened query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 16:22:57
User coded data point as SOC: General disorders and administration site conditions, HLGT: Fatal outcomes, HLT: Death and sudden death, PT: Death, LLT: Unknown cause of death - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 12:38:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 12:38:56
Data point term sent to Coder	System	01 Dec 2020 15:54:17
User entered 'Death (unknown cause)'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 20:49:59
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 15:54:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Dec 2020 15:54:02
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:54:02
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 15:53:33
User entered empty.	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:50:01
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:50:03
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:02:26
User closed query 'per source, 19 nov 2020. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 13:02:21
Query 'per source, 19 nov 2020. please confirm and update' answered with 'updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	19 Jan 2021 23:11:04
User entered '19 Nov 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	19 Jan 2021 23:10:55
User opened query 'per source, 19 nov 2020. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 20:50:52
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 20:50:20
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:50:05
User entered '09 Nov 2020'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:02:28
User entered empty.	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

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US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:12:02
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'End date is after date of death. Please update as appropriate.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'End date is after date of death. Please update as appropriate.' (Site from System).	System	03 Feb 2021 14:16:47
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:02:37
User closed query 'per source, 19 nov 2020. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 13:02:32
Query 'per source, 19 nov 2020. please confirm and update' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	19 Jan 2021 23:11:34
User entered '19 Nov 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	19 Jan 2021 23:10:55
User opened query 'per source, 19 nov 2020. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 20:50:51
User entered '09 Nov 2020'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:02:39
User entered empty.	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

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US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	01 Dec 2020 15:53:33

FDA-CBER-2022-1614-3443955

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:02:43
User entered 'Grade 4 (Grade 4)'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:02:46
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:02:51
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 12:44:33
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'Cause is unknown site is unable to obtain any additional information at this time ' (Site from Safety).	Danyel Johnson (b) (4)	19 Jan 2021 23:07:31
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:36:23
User entered '1'	Danyel Johnson (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 21:01:34
User entered '0'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 21:01:35
User entered '0'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 21:01:23
User entered empty.	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

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US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 21:01:26
User entered empty.	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 21:01:18
User entered empty.	Danyel Johnson (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 21:01:25
User entered empty.	Danyel Johnson (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 21:01:20
User entered '0'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 21:01:28
User entered '0'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 21:01:22
User entered '0'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 21:01:11
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 20:16:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Dec 2020 20:16:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 20:16:04
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 15:53:33
User entered empty.	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 21:01:09
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 20:16:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Dec 2020 20:16:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 20:16:04
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 15:53:33
User entered empty.	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 21:01:07
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 17 Sept 2020 and AE#2 has a start date 09 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:48:39
Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 17 Sept 2020 and AE#2 has a start date 09 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:07:45
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:07:36
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 17 Sept 2020 and AE#2 has a start date 09 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:37:00
User entered 'None (NONE)'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:03:00
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Dec 2020 15:54:02
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:54:02
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Dec 2020 15:53:33
User entered '0'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:03:06
User entered '0'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:03:03
User entered '0'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
User closed query 'Per DM CLR: Outcome = FATAL. Review and ensure this is reflected in End of Study eCRF, if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 06:36:15
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:03:13
Query 'Per DM CLR: Outcome = FATAL. Review and ensure this is reflected in End of Study eCRF, if applicable. Review and update. Else, clarify.' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	19 Jan 2021 23:11:52
User opened query 'Per DM CLR: Outcome = FATAL. Review and ensure this is reflected in End of Study eCRF, if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:59:12
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 15:54:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Dec 2020 15:54:02
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	01 Dec 2020 15:54:02
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 15:53:33
User entered empty.	Danyel Johnson (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:03:16
User entered empty.	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Per CDM Re-query: Site response noted. In SAE Narrative, site reports subject has history of severe alcohol addiction, mental health issues, and suicidal tendencies. However, since this is a 'Fatal' outcome, and these details were reported by the someone other than the subject, please provide any documentation and/or related medical records to support this in EDC and have on site as source document. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:54:06
Query 'Per CDM Re-query: Site response noted. In SAE Narrative, site reports subject has history of severe alcohol addiction, mental health issues, and suicidal tendencies. However, since this is a 'Fatal' outcome, and these details were reported by the someone other than the subject, please provide any documentation and/or related medical records to support this in EDC and have on site as source document. Thank you.' answered with 'None of the reported history was disclosed by the subject. The site does not have medical records for subject ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	10 Feb 2021 18:31:49
User opened query 'Per CDM Re-query: Site response noted. In SAE Narrative, site reports subject has history of severe alcohol addiction, mental health issues, and suicidal tendencies. However, since this is a 'Fatal' outcome, and these details were reported by the someone other than the subject, please provide any documentation and/or related medical records to support this in EDC and have on site as source document. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 17:53:55

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US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Narrative

Audit	User	Time (GMT)
Query 'Per CDM Re-query: Site response noted. In SAE Narrative, site reports subject has history of severe alcohol addiction and w/ suicidal tendencies. However, since this is a 'Fatal' outcome, and these details were reported by the someone other than the subject, please provide any documentation and/or related medical records to support this in EDC and have on site as source document. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 17:53:29
User opened query 'Per CDM Re-query: Site response noted. In SAE Narrative, site reports subject has history of severe alcohol addiction and w/ suicidal tendencies. However, since this is a 'Fatal' outcome, and these details were reported by the someone other than the subject, please provide any documentation and/or related medical records to support this in EDC and have on site as source document. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 17:46:09
User closed query 'Per DM CLR: SAE Narrative = SEVER ALCOHOL ADDICTION AND MENTAL HEALTH ISSUES IN THE PAST WITH SUICIDAL TENDENCIES. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 17:46:09
Query 'PV Query: Please provide/confirm the cause of death. If the information will not be available at anytime in the future, please state so in your response.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 20:51:58
Query 'PV Query: Please provide the cause of death from the death certificate when available.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 20:49:47
User opened query 'PV Query: Please provide the cause of death from the death certificate when available.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 20:49:36
User opened query 'PV Query: Please provide/confirm the cause of death. If the information will not be available at anytime in the future, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:18:37
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:04:29

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US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify whether worsening hypertension treated on 08-OCT-2020 meets criteria of AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 12:44:40
Query 'Per DM CLR: SAE Narrative = SEVER ALCOHOL ADDICTION AND MENTAL HEALTH ISSUES IN THE PAST WITH SUICIDAL TENDENCIES. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'This was a verbal report by subjects estranged wife. Please advise if this should be added.' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	19 Jan 2021 23:10:43
Query 'PV Query: Please clarify whether worsening hypertension treated on 08-OCT-2020 meets criteria of AE/SAE.' answered with 'AE of worsening hypertension noted ' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	19 Jan 2021 23:08:13
User opened query 'Per DM CLR: SAE Narrative = SEVER ALCOHOL ADDICTION AND MENTAL HEALTH ISSUES IN THE PAST WITH SUICIDAL TENDENCIES. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:59:28
User opened query 'PV Query: Please clarify whether worsening hypertension treated on 08-OCT-2020 meets criteria of AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:37:47
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:26:51
User closed query 'PV Query: Please confirm if Severe alcohol addiction, Mental health issues, and Suicidal tendencies mentioned in SAE narrative are considered medical history. If so please consider updating medical history with these conditions.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:26:48
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:26:45
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'Cause is unknown at' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:07:02

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US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if Severe alcohol addiction, Mental health issues, and Suicidal tendencies mentioned in SAE narrative are considered medical history. If so please consider updating medical history with these conditions.' answered with 'Information was given by subjects ex wife and not provided by the subject' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:06:50
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'Unable to obtain' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:06:18
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 16:23:26
User opened query 'PV Query: Please confirm if Severe alcohol addiction, Mental health issues, and Suicidal tendencies mentioned in SAE narrative are considered medical history. If so please consider updating medical history with these conditions.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 16:23:19
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 16:23:06

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Narrative

Audit	User	Time (GMT)
User entered '50 y/o randomized male who received the first dose of blinded mRNA-1273 or placebo for SARS-CoV-2 vaccination on 8/20/2020 and his second, final dose of study drug, on 09/17/ 2020. 11/30/2020 The site sent an email to inquire about several missed diary entries. The site received notification via email from his wife that the subject had passed away on 11/19/2020. The site contacted the wife at the number given in the email to obtain information surrounding the subject's death. Per the wife's report the subject was (b) (6) The cause of death is currently listed as pending on the death certificate labs were obtained at the coroner's office and will be sent for processing which per wife's report can take up to 90 days. The wife reported that the subject has battled sever alcohol addiction and mental health issues in the past with suicidal tendencies and feels that this contributed to the subject's death.'	Danyel Johnson (b) (4) (b) (4)	01 Dec 2020 15:53:33

FDA-CBER-2022-1614-3443980

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	01 Dec 2020 15:53:33

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '0'	System	01 Dec 2020 15:54:02

US3832237
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:01:21
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59

FDA-CBER-2022-1614-3443983

US3832237

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:01:21

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'please enter concomitant procedure log' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 15:13:38
Query 'please enter concomitant procedure log' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	26 Jan 2021 15:47:38
User opened query 'please enter concomitant procedure log' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 17:55:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:34

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:56:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:56:19
Data point term sent to Coder	System	20 Aug 2020 15:55:38
User entered 'Sertaline'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

FDA-CBER-2022-1614-3443985

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Anxiety'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '200'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:01:11
User entered 'un UNK 2016'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '804 (804)'	System	20 Aug 2020 15:54:56

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:56:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:56:19
Data point term sent to Coder	System	20 Aug 2020 15:55:41
User entered 'Losartan'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '50'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:01:11
User entered 'un UNK 2014'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:28:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'End Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'End Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '08 Oct 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:28:39
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '804 (804)'	System	20 Aug 2020 15:55:17

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:56:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:56:19
Data point term sent to Coder	System	20 Aug 2020 15:55:41
User entered 'Metoprolol'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '25'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:01:11
User entered 'un Dec 2019'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

FDA-CBER-2022-1614-3444031

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '804 (804)'	System	20 Aug 2020 15:55:39

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:57:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:57:24
Data point term sent to Coder	System	20 Aug 2020 15:56:44
User entered 'Clonidine'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Insomnia'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '.1'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:01:11
User entered 'un Dec 2019'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '804 (804)'	System	20 Aug 2020 15:56:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:59:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:59:26
Data point term sent to Coder	System	20 Aug 2020 15:57:51
User entered 'Vitamin D3'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User closed query 'Per CDM Re-Query: Site response noted; however neither the MH indication nor the CM indication have been updated. Please review and reconcile the data as per previous query. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 12:26:17
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
Query 'Per CDM Re-Query: Site response noted; however neither the MH indication nor the CM indication have been updated. Please review and reconcile the data as per previous query. Thank you.' answered with 'Please see log line 4 of Med Hx' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	19 Feb 2021 18:03:27
User opened query 'Per CDM Re-Query: Site response noted; however neither the MH indication nor the CM indication have been updated. Please review and reconcile the data as per previous query. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 10:33:41
User closed query 'Per CDM: Log Line 4 of Medical History log indicates 'Vitamin D Deficiency'. Please verify data and consider updating indication field on this form to reflect 'Vitamin D Deficiency' in order to reconcile with condition recorded on MH form. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 10:33:41
Query 'Per CDM: Log Line 4 of Medical History log indicates 'Vitamin D Deficiency'. Please verify data and consider updating indication field on this form to reflect 'Vitamin D Deficiency' in order to reconcile with condition recorded on MH form. Thank you.' answered with 'corrected' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 19:30:32
User opened query 'Per CDM: Log Line 4 of Medical History log indicates 'Vitamin D Deficiency'. Please verify data and consider updating indication field on this form to reflect 'Vitamin D Deficiency' in order to reconcile with condition recorded on MH form. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 15:53:18
User entered 'Vitamin D3 Deficiency'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit recorded in the other specify is can be one of the available option 'capsule' from the drop down list. Please update accordingly. Else Clarify.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 12:47:29
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit recorded in the other specify is can be one of the available option 'capsule' from the drop down list. Please update accordingly. Else Clarify.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Oct 2020 17:06:52
User entered 'capsule (CAPSULE)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	09 Oct 2020 17:06:29
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit recorded in the other specify is can be one of the available option 'capsule' from the drop down list. Please update accordingly. Else Clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:17:35
User entered 'Other (OTHER)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	09 Oct 2020 17:06:29
User entered 'capsule'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:01:11
User entered 'un Apr 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '804 (804)'	System	20 Aug 2020 15:57:45

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 11:45:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 11:45:47
Data point term sent to Coder	System	17 Sep 2020 14:53:55
User entered 'Benadryl'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:25:41
Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 20:25:59
User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:25:48
User entered 'Acid Reflux with Nausea'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 25 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:25:44
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 25 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	03 Nov 2020 21:20:18
User entered '25' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	03 Nov 2020 21:19:54
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 25 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:24:51
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'mg (mg)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	03 Nov 2020 21:19:54
User entered 'tablet (TABLET)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'UN UNK 2017'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	17 Sep 2020 14:53:50

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE HYDROCHLORIDE, PRODUCTSYNONYM: BUSPAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 14:56:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 14:56:41
Data point term sent to Coder	System	17 Sep 2020 14:56:00
User entered 'BuSpar'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Anxiety'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '10'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered 'UN Jan 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	17 Sep 2020 14:55:04

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:04:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:04:01
Data point term sent to Coder	System	15 Oct 2020 14:30:13
User entered 'Losartan'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Worsening of Hypertension'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '100'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'mg (mg)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'once daily (QD)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '08 Oct 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '1'	System	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered '804 (804)'	System	15 Oct 2020 14:30:12

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:53:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:53:44
Data point term sent to Coder	System	02 Nov 2020 16:20:53
User entered 'Influenza Vaccine'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Influenza Prophylaxis'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '.5'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'mL (mL)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'once (ONCE)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Intramuscular (INTRAMUSCULAR)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Per CDM: As per section 6.4.3. of 'Protocol Amendment 6', 'Seasonal Influenza Vaccine' is not permitted within 14 days before or after any dose of IP. In this instance, Site reports 'Seasonal Influenza Vaccine' was given on 13Oct2020, which is 26 days after 2nd Dose, and is well within the allotted window per Protocol. However, since it is close to this narrow time-frame (only 12 days), kindly confirm date of 'Seasonal Influenza Vaccine'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 10:38:04
User closed query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
Query 'Per CDM: As per section 6.4.3. of 'Protocol Amendment 6', 'Seasonal Influenza Vaccine' is not permitted within 14 days before or after any dose of IP. In this instance, Site reports 'Seasonal Influenza Vaccine' was given on 13Oct2020, which is 26 days after 2nd Dose, and is well within the allotted window per Protocol. However, since it is close to this narrow time-frame (only 12 days), kindly confirm date of 'Seasonal Influenza Vaccine'. Thank you.' answered with 'Date of death is 19 Nov 2020' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 19:36:38
User opened query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User opened query 'Per CDM: As per section 6.4.3. of 'Protocol Amendment 6', 'Seasonal Influenza Vaccine' is not permitted within 14 days before or after any dose of IP. In this instance, Site reports 'Seasonal Influenza Vaccine' was given on 13Oct2020, which is 26 days after 2nd Dose, and is well within the allotted window per Protocol. However, since it is close to this narrow time-frame (only 12 days), kindly confirm date of 'Seasonal Influenza Vaccine'. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 15:46:37
User entered '13 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 16:20:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 16:20:48
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:48
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 16:20:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'End Date is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'End Date is after Date of Death. Please review and reconcile.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '13 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

FDA-CBER-2022-1614-3444142

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:01:21
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User entered empty.	System	02 Nov 2020 16:20:42

US3832237
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 10:01:21
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	26 Jan 2021 15:05:09

US3832237
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:01:21
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:36:59
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	09 Feb 2021 20:36:31
User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '19 Nov 2020'	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 14:16:47

US3832237
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:01:21
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:36:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	29 Apr 2021 02:21:34
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	21 Apr 2021 19:51:36
User entered 'Death (DEATH)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	21 Apr 2021 19:51:36
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	21 Apr 2021 19:50:07
Signature has been broken.	Danyel Johnson (b) (4) (b) (4)	21 Apr 2021 19:50:07
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	21 Apr 2021 19:50:07
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Death (DEATH)'	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 14:16:47

US3832237

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:01:21

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)	01 May 2021 21:27:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:36:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	29 Apr 2021 02:21:34
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	21 Apr 2021 19:51:54
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	21 Apr 2021 19:51:54
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	21 Apr 2021 19:51:36
Signature has been broken.	Danyel Johnson (b) (4) (b) (4)	21 Apr 2021 19:50:07
User entered 'Death Unknown Cause' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	21 Apr 2021 19:50:07
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 14:16:47

US3832237
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:01:21
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:36:59
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:34
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User closed query 'per CDM RQ: please update data to "Adverse Event", or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:29:37
Query 'per CDM RQ: please update data to "Adverse Event", or otherwise clarify' answered with 'Corrected per query' (Site from DM).	Danyel Johnson (b) (4)	21 Apr 2021 20:34:22
Signature has been broken.	Danyel Johnson (b) (4)	21 Apr 2021 20:33:30
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	21 Apr 2021 20:33:30
User opened query 'per CDM RQ: please update data to "Adverse Event", or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 20:30:43
User closed query 'Per CDMRQ: "Death-unknown cause" is listed as an Adverse Event. Adverse event must be captured on liine 4 per CCGs.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 20:30:43
Query 'Per CDMRQ: "Death-unknown cause" is listed as an Adverse Event. Adverse event must be captured on liine 4 per CCGs.' answered with 'Updated per review' (Site from DM).	Danyel Johnson (b) (4)	21 Apr 2021 19:50:18
User opened query 'Per CDMRQ: "Death-unknown cause" is listed as an Adverse Event. Adverse event must be captured on liine 4 per CCGs.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 14:25:43
User closed query 'Per CDM: ""Death-Unknown Cause" is listed as an AE with outcome of death, therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event." ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 14:25:43

FDA-CBER-2022-1614-3444151

US3832237
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:01:21
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Query 'Per CDM: ""Death-Unknown Cause" is listed as an AE with outcome of death, therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event." ' answered with 'Cause is unknown' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	19 Apr 2021 17:11:24
User opened query 'Per CDM: ""Death-Unknown Cause" is listed as an AE with outcome of death, therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event." ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 16:13:44
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Unknown (UNKNOWN)'	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 14:16:47

US3832237
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:01:21
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:36:59
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered empty.	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 14:16:47

US3832237
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:01:21
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:36:59
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User closed query 'Per CDM: It appears there is a typo on the year. Please verify data and update to '19Nov2020' if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:54:27
Query 'Per CDM: It appears there is a typo on the year. Please verify data and update to '19Nov2020' if appropriate. Thank you.' answered with 'updated ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 20:36:37
User closed query 'Date of Death is prior to Date of Randomization. Please correct.' (Site from System).	System	09 Feb 2021 20:36:31
User closed query 'Date of Death is prior to Date of Informed Consent. Please correct.' (Site from System).	System	09 Feb 2021 20:36:31
User entered '19 Nov 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 20:36:31
User opened query 'Per CDM: It appears there is a typo on the year. Please verify data and update to '19Nov2020' if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 14:04:32
User opened query 'Date of Death is prior to Date of Randomization. Please correct.' (Site from System).	System	03 Feb 2021 14:16:47
User opened query 'Date of Death is prior to Date of Informed Consent. Please correct.' (Site from System).	System	03 Feb 2021 14:16:47
User entered '19 Nov 2019'	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 14:16:47

US3832237
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:01:21
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:51
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:36:59
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered 'Unknown (UNK)'	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 14:16:47

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'USA-US100-2020-MRNA-1273-P301000008'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Yes (Y)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Yes (Y)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Gowdhami'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Mohan'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered '1655 E. Greenville St'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Anderson'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'SC'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered '29621'	System	02 Dec 2020 18:03:19

FDA-CBER-2022-1614-3444169

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:46:15
User entered 'US'	System	02 Dec 2020 18:03:44

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '3'	System	20 Jan 2021 12:46:23
User entered '2'	System	16 Dec 2020 17:27:27
User entered '1'	System	02 Dec 2020 18:03:44

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'USA-US100-2020-MRNA-1273-P301000008'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Yes (Y)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Yes (Y)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Gowdhami'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Mohan'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered '1655 E. Greenville St'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Anderson'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'SC'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered '29621'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:46:15
User entered 'US'	System	02 Dec 2020 18:03:44

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '3'	System	20 Jan 2021 12:46:23
User entered '2'	System	16 Dec 2020 17:27:27
User entered '1'	System	02 Dec 2020 18:03:44

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 10:01:21
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
User entered '02/Dec/2020 13:03'	System	02 Dec 2020 18:03:44

US3832237

Folder: SAE USA-US100-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:46:15
User entered '1'	(b) (4), (b) (6)	02 Dec 2020 18:03:44

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'USA-US100-2020-MRNA-1273-P301000008'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Yes (Y)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Yes (Y)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Gowdhami'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Mohan'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered '1655 E. Greenville St'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Anderson'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'SC'	System	02 Dec 2020 18:03:19

FDA-CBER-2022-1614-3444202

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered '29621'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:46:15
User entered 'US'	System	02 Dec 2020 18:03:44

FDA-CBER-2022-1614-3444204

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '3'	System	20 Jan 2021 12:46:23
User entered '2'	System	16 Dec 2020 17:27:27
User entered '1'	System	02 Dec 2020 18:03:44

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 10:01:21
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
User entered '16/Dec/2020 11:27'	System	16 Dec 2020 17:27:27

US3832237

Folder: SAE USA-US100-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:46:15
User entered '1'	(b) (4), (b) (6)	16 Dec 2020 17:27:27

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'USA-US100-2020-MRNA-1273-P301000008'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Yes (Y)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Yes (Y)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'No (N)'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Gowdhami'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Mohan'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered '1655 E. Greenville St'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'Anderson'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered 'SC'	System	02 Dec 2020 18:03:19

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:38
User entered '29621'	System	02 Dec 2020 18:03:19

FDA-CBER-2022-1614-3444221

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:46:15
User entered 'US'	System	02 Dec 2020 18:03:44

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 10 Jun 2021 10:01:21
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:38:38
User entered '3'	System	20 Jan 2021 12:46:23
User entered '2'	System	16 Dec 2020 17:27:27
User entered '1'	System	02 Dec 2020 18:03:44

US3832237
Folder: SAE USA-US100-2020-MRNA-1273-P301000008
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 10:01:21
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:06:00
User entered '20/Jan/2021 07:46'	System	20 Jan 2021 12:46:23

FDA-CBER-2022-1614-3444224

US3832237

Folder: SAE USA-US100-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:01:21

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)	26 Apr 2021 21:34:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:06:00
User entered '1'	(b) (4), (b) (6)	20 Jan 2021 12:46:23