US3232048 (Prod: MediSync Clinical Research Hattiesburg Clinic)

Generated By: KC Joubran

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US3232048
Form: Participant Creation
Data signed: (b) (4) **05 Mar 2021 19:05:45**
Generated On: 09 Jun 2021 16:04:06

Participant ID	US3232048

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0646850

US3232048
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0646851

US3232048
Folder: Screening
Form: Demographics
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
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-2022-1614-0646852

US3232048
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Date of Informed Consent *(dd MMM yyyy)*	14 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-2022-1614-0646853

US3232048
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646854

US3232048
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **05 Mar 2021 19:05:47**
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Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0646855

US3232048
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Condition	ASTIGMATISM BILATERAL (EYEGLASSES)
Start date (dd MMM yyyy)	UN UNK 1959
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1959
Start Year (derived)	1959
Stop Month and Year (derived)	
Stop Year (derived)	

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US3232048
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	18 DEC 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0646857

US3232048
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Condition	IRREGULAR HEART BEAT
Start date (dd MMM yyyy)	16 MAY 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	16 MAY 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	MAY 2019
Stop Year (derived)	2019

FDA-CBER-2022-1614-0646858

US3232048
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	19 DEC 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes No
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

FDA-CBER-2022-1614-0646859

US3232048
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Condition	INGUINAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

FDA-CBER-2022-1614-0646860

US3232048
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Condition	GERD
Start date (dd MMM yyyy)	24 SEP 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)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0646861

US3232048
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646862

US3232048
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Condition	BPH
Start date (dd MMM yyyy)	19 DEC 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	23 NOV 2015
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2013
Start Year (derived)	2013
Stop Month and Year (derived)	NOV 2015
Stop Year (derived)	2015

FDA-CBER-2022-1614-0646863

US3232048
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Condition	AMYOTROPHIC LATERAL SCLEROSIS
Start date (dd MMM yyyy)	2 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-2022-1614-0646864

US3232048
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Condition	INSOMNIA
Start date (dd MMM yyyy)	4 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0646865

US3232048
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Condition	MEMORY CHANGES
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-2022-1614-0646866

US3232048
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	14 AUG 2020
Time of assessment *(00:00-23:59)*	9:58 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 9:58
Height *(xxx.x)*	160 cm
Weight *(xxx.x)*	67.5 kg
BMI *(xxx.x)*	26.36719 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3232048
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:05:47**
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Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	14 AUG 2020

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

FDA-CBER-2022-1614-0646868

US3232048
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **05 Mar 2021 19:05:47**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐ No ■
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ■
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ■
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ■
Other	Yes ☐ No ■
Specify	

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

US3232048
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **05 Mar 2021 19:05:47**
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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	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

FDA-CBER-2022-1614-0646870

US3232048
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0646871

US3232048
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

What was the date of randomization? *(dd MMM yyyy)*	21 AUG 2020
What was the participant's randomization number?	187263
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ☐ >=18 and <65 years and at risk ☐ >=65 years ■

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

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

FDA-CBER-2022-1614-0646872

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0646873

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

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)*	
Time of assessment *(00:00-23:59)*	
Vital Signs Date and Time (derived)	
Temperature *(xxx.x)*	
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	
Pulse units	
Respiratory Rate *(xxx)*	
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	
Systolic Blood Pressure units	
Diastolic Blood Pressure *(xxx)*	
Diastolic Blood Pressure units	

FDA-CBER-2022-1614-0646874

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

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)*	21 AUG 2020
Time of assessment *(00:00-23:59)*	11:52 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 11:52
Temperature *(xxx.x)*	97.0 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0646875

US3232048
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

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

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

FDA-CBER-2022-1614-0646876

US3232048
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

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)*	21 AUG 2020
What was the treatment time? *(00:00-23:59)*	11:00 (24 HR)
Treatment Date and Time (derived)	21 AUG 2020 11:00
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-2022-1614-0646877

US3232048
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	21 AUG 2020
Collection time *(00:00-23:59)*	11:18 (24 HR)
Collection date and time (derived)	21 AUG 2020 11:18

FDA-CBER-2022-1614-0646878

US3232048
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Collection date *(dd MMM yyyy)*			21 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	21 AUG 2020 10:30
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0646879

US3232048
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:05:47**
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Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0646880

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 AUG 2020 11:38
PC Open Date & Time	21 AUG 2020 11:20
PC Close Date & Time	21 AUG 2020 13:50

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 AUG 2020 19:42
PC Open Date & Time	21 AUG 2020 14:45
PC Close Date & Time	22 AUG 2020 11:59

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06

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**	97.5 °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	22 AUG 2020 19:51
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06

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**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	23 AUG 2020 19:46
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-0646884

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	24 AUG 2020 20:00
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-0646885

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.5 °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	25 AUG 2020 20:14
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °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	26 AUG 2020 20:12
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	27 AUG 2020 20:23
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06

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	21 AUG 2020 11:39
PC Open Date & Time	21 AUG 2020 11:20
PC Close Date & Time	21 AUG 2020 13:50

FDA-CBER-2022-1614-0646889

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	21 AUG 2020 19:43
PC Open Date & Time	21 AUG 2020 14:45
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-0646890

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	22 AUG 2020 19:51
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-0646891

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	23 AUG 2020 19:46
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-0646892

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06

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	24 AUG 2020 20:01
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06

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	25 AUG 2020 20:14
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-0646894

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06

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	26 AUG 2020 20:13
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-0646895

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	27 AUG 2020 20:23
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-0646896

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 ☐

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	21 AUG 2020 11:40
PC Open Date & Time	21 AUG 2020 11:20
PC Close Date & Time	21 AUG 2020 13:50

FDA-CBER-2022-1614-0646898

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 ☐

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	21 AUG 2020 19:44
PC Open Date & Time	21 AUG 2020 14:45
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-0646900

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 ■

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06

	Yes
PC Time stamp	22 AUG 2020 19:52
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-0646902

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 ■

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06

	Yes ☐
PC Time stamp	23 AUG 2020 19:46
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-0646904

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 ■

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06

	Yes ☐
PC Time stamp	24 AUG 2020 20:01
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-0646906

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 ■

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06

	Yes ☐
PC Time stamp	25 AUG 2020 20:15
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-0646908

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06

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-2022-1614-0646909

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06

	Yes ☐
PC Time stamp	26 AUG 2020 20:13
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

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

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06

	Yes
PC Time stamp	27 AUG 2020 20:23
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-0646912

US3232048
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

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

US3232048
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646914

US3232048
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	4 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-2022-1614-0646915

US3232048
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646916

US3232048
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 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-2022-1614-0646917

US3232048
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646918

US3232048
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0646919

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	18 SEP 2020
Time of assessment *(00:00-23:59)*	09:40 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 09:40
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	60 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0646920

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	18 SEP 2020
Time of assessment *(00:00-23:59)*	12:04 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 12:04
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	83 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	60 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0646921

US3232048
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	18 SEP 2020

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

FDA-CBER-2022-1614-0646922

US3232048
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

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)*	18 SEP 2020
What was the treatment time? *(00:00-23:59)*	11:42 (24 HR)
Treatment Date and Time (derived)	18 SEP 2020 11:42
Which arm was used to give treatment?	Left Arm ☐ Right Arm ■
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0646923

US3232048
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	18 SEP 2020
Collection time *(00:00-23:59)*	10:00 (24 HR)
Collection date and time (derived)	18 SEP 2020 10:00

FDA-CBER-2022-1614-0646924

US3232048
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Collection date *(dd MMM yyyy)*			18 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:55	18 SEP 2020 09:55
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0646925

US3232048
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646926

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.3 °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	18 SEP 2020 12:02
PC Open Date & Time	18 SEP 2020 12:02
PC Close Date & Time	18 SEP 2020 14:32

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 SEP 2020 18:46
PC Open Date & Time	18 SEP 2020 15:27
PC Close Date & Time	19 SEP 2020 11:59

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06

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

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06

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**	97.8 °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 18:16
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06

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**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 SEP 2020 20:00
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06

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**	97.7 °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	22 SEP 2020 20:38
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06

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**	97.7 °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	23 SEP 2020 22:27
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06

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**	98.0 °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	24 SEP 2020 19:09
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06

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	18 SEP 2020 12:03
PC Open Date & Time	18 SEP 2020 12:02
PC Close Date & Time	18 SEP 2020 14:32

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US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06

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 18:47
PC Open Date & Time	18 SEP 2020 15:27
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-0646936

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	19 SEP 2020 20:00
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-0646937

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06

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 18:16
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-0646938

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06

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	21 SEP 2020 20:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-0646939

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06

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	22 SEP 2020 20:39
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-0646940

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06

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	23 SEP 2020 22:27
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-0646941

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06

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 19:09
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-0646942

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 ☐

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	18 SEP 2020 12:03
PC Open Date & Time	18 SEP 2020 12:02
PC Close Date & Time	18 SEP 2020 14:32

FDA-CBER-2022-1614-0646944

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 ☐

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 SEP 2020 18:47
PC Open Date & Time	18 SEP 2020 15:27
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-0646946

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 ■

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646948

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 ■

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06

	Yes
PC Time stamp	20 SEP 2020 18:18
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-0646950

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 ■

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06

	Yes ☐
PC Time stamp	21 SEP 2020 20:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-0646952

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 ■

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06

	Yes ☐
PC Time stamp	22 SEP 2020 20:39
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-0646954

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 ■

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06

	Yes ☐
PC Time stamp	23 SEP 2020 22:28
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-0646956

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 ■

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06

	Yes ☐
PC Time stamp	24 SEP 2020 19:10
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-0646958

US3232048
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 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-2022-1614-0646959

US3232048
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646960

US3232048
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 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-2022-1614-0646961

US3232048
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646962

US3232048
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 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-2022-1614-0646963

US3232048
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646964

US3232048
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646965

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	16 OCT 2020
Time of assessment *(00:00-23:59)*	10:40 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 10:40
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0646966

US3232048
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

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

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

FDA-CBER-2022-1614-0646967

US3232048
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	16 OCT 2020
Collection time *(00:00-23:59)*	11:00 (24 HR)
Collection date and time (derived)	16 OCT 2020 11:00

FDA-CBER-2022-1614-0646968

US3232048
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:05:47**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646969

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06

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 06:34:13
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

FDA-CBER-2022-1614-0646970

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06

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	28 OCT 2020 17:11:53
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

FDA-CBER-2022-1614-0646971

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06

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	04 NOV 2020 07:49:54
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

FDA-CBER-2022-1614-0646972

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 09:39:07
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

FDA-CBER-2022-1614-0646973

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 09:07:57
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

FDA-CBER-2022-1614-0646974

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 16:22:21
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

FDA-CBER-2022-1614-0646975

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please 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 ☐

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06

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	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

FDA-CBER-2022-1614-0646977

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 16:22:11
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

FDA-CBER-2022-1614-0646978

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646979

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06

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	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

FDA-CBER-2022-1614-0646980

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

US3232048
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3232048
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646983

US3232048
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646984

US3232048
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0646985

US3232048
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 16:04:06

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ☐ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐ No ☐

FDA-CBER-2022-1614-0646986

US3232048
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 16:04:06

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-0646987

US3232048
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06

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-2022-1614-0646988

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)	_____

US3232048
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **05 Mar 2021 19:05:45**
Generated On: 09 Jun 2021 16:04:06

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-0646992

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **02 Apr 2021 13:38:49**
Generated On: 09 Jun 2021 16:04:06

AEID	USA-US105-2020-MRNA-1273-P301000003
Adverse event	COMPLICATION OF AMYOTROPHIC LATERAL SCLEROSIS
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)*	05 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)*	12 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	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	True
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	

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **02 Apr 2021 13:38:49**
Generated On: 09 Jun 2021 16:04:06

	PATIENT WAS PLACED IN HOSPICE ON NOVEMBER 19, 2020 IN HOME SECONDARY TO DYSPHAGIA WITH PEG TUBE PLACEMENT AND PROGRESSION OF ALS. PATIENT DIED AT HOME ON DECEMBER 12, 2020 AT 2 AM. PENDING DEATH CERTIFICATE FOR CAUSE OF DEATH.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

FDA-CBER-2022-1614-0646995

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **02 Apr 2021 13:38:49**
Generated On: 09 Jun 2021 16:04:06

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

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

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **02 Apr 2021 13:38:49**
Generated On: 09 Jun 2021 16:04:06

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

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

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

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

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

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US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

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

	Intramuscular ☐ Respiratory (Inhalation) ☐ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

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

	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)*	14 APR 2016
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

Name of Medication	CARVEDILOL
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 ☐

	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)*	17 DEC 2019
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

Name of Medication	CHOLECOLEFICEROL
Prophylaxis	Yes ■ No ☐
Indication	MAINTENANCE
Dose per administration	1000
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)*	12 MAY 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

Name of Medication	GUANFACINE
Prophylaxis	Yes ○ No ●
Indication	HYPERTENSION
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 ○

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	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)*	6 DEC 2019
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

Name of Medication	MAGNESIUM
Prophylaxis	Yes ■ No ☐
Indication	MAINTENANCE
Dose per administration	235
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)*	3 MAR 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ■ No ☐
Indication	MAINTENANCE
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 ☐

	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)*	3 MAR 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

Name of Medication	PROBIOTIC
Prophylaxis	Yes ■ No ☐
Indication	MAINTENANCE
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 ☐

	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)*	3 MAR 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

Name of Medication	QUETIAPINE
Prophylaxis	Yes ○ No ●
Indication	INSOMNIA
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 ○

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	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)*	4 FEB 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

Name of Medication	RILUZOLE
Prophylaxis	Yes ○ No ●
Indication	ALS
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 ○

	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)*	17 DEC 2019
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

Name of Medication	FLUZONE HIGH DOSE
Prophylaxis	Yes ■ No ☐
Indication	INFLUENZA VACCINE
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 ☐

	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)*	2 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	2 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 ☐

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

Name of Medication	HYCOSARMINE SULFATE
Prophylaxis	Yes ○ No ●
Indication	SECRETIONS
Dose per administration	.125
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 ○

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ■
If route of administration is Other, specify	SUBLINGUAL
Start date *(dd MMM yyyy)*	23 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3232048
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

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US3232048
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **05 Mar 2021 19:05:46**
Generated On: 09 Jun 2021 16:04:06

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
10 DEC 2020	PATIENT RECEIVED PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBE	Adverse Event	

US3232048
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 16:04:06

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

FDA-CBER-2022-1614-0647027

US3232048
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **23 Apr 2021 15:21:01**
Generated On: 09 Jun 2021 16:04:06

Date of study discontinuation/completion *(dd MMM yyyy)*	12 DEC 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)*	12 DEC 2020
Was autopsy performed?	Yes ☐ No ■ Unknown ☐

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US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

SAEID	USA-US105-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ■ No ☐
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

SAEID	USA-US105-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ■ No ☐
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/DEC/2020 10:25
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

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

SAEID	USA-US105-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ■ No ☐
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/DEC/2020 13:56
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

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

SAEID	USA-US105-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ■ No ☐
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	17/DEC/2020 19:10
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

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

SAEID	USA-US105-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ■ No ☐
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/DEC/2020 15:37
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

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Data signed: (b) (4) **12 Mar 2021 19:49:53**
Generated On: 09 Jun 2021 16:04:06

SAEID	USA-US105-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ■ No ☐
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/MAR/2021 12:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3232048 (Prod: MediSync Clinical Research Hattiesburg Clinic)

US3232048
Form: Participant Creation
Generated On: 09 Jun 2021 16:04:06
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'US3232048'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 14:09:31

FDA-CBER-2022-1614-0647036

US3232048
Form: Participant Creation
Generated On: 09 Jun 2021 16:04:06

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647037

US3232048
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:01

FDA-CBER-2022-1614-0647038

US3232048
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 14:09:32

FDA-CBER-2022-1614-0647039

US3232048
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Clinic (Clinic)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:01

FDA-CBER-2022-1614-0647040

US3232048
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'SCRN'	(b) (4), (b) (6) System	21 Aug 2020 20:08:01

FDA-CBER-2022-1614-0647041

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered (b) (6) 1947'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 14:09:33

FDA-CBER-2022-1614-0647042

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '73'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647043

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
	(b) (4), (b) (6)	
User entered 'YEARS'	System	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647044

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '73'	(b) (4), (b) (6) System	21 Aug 2020 16:26:53

FDA-CBER-2022-1614-0647045

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Male (M)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647046

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647047

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647048

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647049

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647050

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647051

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647053

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647054

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647055

US3232048
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:04:06
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:11

FDA-CBER-2022-1614-0647056

US3232048
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:04:06
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '14 Aug 2020'	Adreanna Pou (b) (4) (b) (4)	21 Aug 2020 16:26:53

FDA-CBER-2022-1614-0647057

US3232048
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:04:06
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Aug 2020'	(b) (4), (b) (6) System	21 Aug 2020 16:26:53

FDA-CBER-2022-1614-0647058

US3232048
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:04:06
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2020'	(b) (4), (b) (6) System	21 Aug 2020 16:26:53

FDA-CBER-2022-1614-0647059

US3232048
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:04:06
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Amendment 2 (2)'	Adreanna Pou (b) (4) (b) (4)	21 Aug 2020 16:26:53

FDA-CBER-2022-1614-0647060

US3232048
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:04:06
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	21 Aug 2020 16:26:53

FDA-CBER-2022-1614-0647061

US3232048
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:04:06
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	21 Aug 2020 16:26:53

FDA-CBER-2022-1614-0647062

US3232048
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:04:06
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	21 Aug 2020 16:26:53

US3232048
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:04:06
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Adreanna Pou (b) (4) (b) (4)	21 Aug 2020 16:26:53

FDA-CBER-2022-1614-0647064

US3232048
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:04:06
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 14:09:32

FDA-CBER-2022-1614-0647065

US3232048
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:04:06
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 16:27:09

FDA-CBER-2022-1614-0647066

US3232048
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 16:04:06
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	21 Aug 2020 16:27:09

FDA-CBER-2022-1614-0647067

US3232048
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 16:04:06
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:51
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:24

US3232048
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Oct 2020 15:21:36
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 10:48:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 10:48:42
Data point term sent to Coder	System	24 Sep 2020 17:04:51
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' answered with 'UPDATED PER QUERY RESOLUTION' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	24 Sep 2020 17:04:23
Coding entries removed.	Adreanna Pou (b) (4) (b) (4)	24 Sep 2020 17:04:20
User entered 'ASTIGMATISM BILATERAL (EYEGLASSES)' reason for change: Per Query Resolution	Adreanna Pou (b) (4) (b) (4)	24 Sep 2020 17:04:20
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Sep 2020 13:52:45
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Eyeglasses wearer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 06:34:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 06:34:48
Data point term sent to Coder	System	26 Aug 2020 06:34:02

US3232048
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Eyeglasses wearer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 06:33:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 06:33:47
Query 'DM-Coding: please clarify is this Eyeglasses wearer/Eyeglasses therapy? Please update this term in accordance with your answer.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	26 Aug 2020 06:33:41
User opened query 'DM-Coding: please clarify is this Eyeglasses wearer/Eyeglasses therapy? Please update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4) (b) (4)	25 Aug 2020 13:03:44
Data point term sent to Coder	System	24 Aug 2020 14:52:47
User entered 'eyeglasses'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:09

FDA-CBER-2022-1614-0647070

US3232048
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:04:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'un UNK 1959'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:09

FDA-CBER-2022-1614-0647071

US3232048
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:09

FDA-CBER-2022-1614-0647072

US3232048
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:04:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:09

FDA-CBER-2022-1614-0647073

US3232048
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:04:06
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:09

FDA-CBER-2022-1614-0647074

US3232048
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:04:06
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:09

FDA-CBER-2022-1614-0647075

US3232048
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:04:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Jan 1959'	(b) (4), (b) (6) System	24 Aug 2020 14:52:09

FDA-CBER-2022-1614-0647076

US3232048
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:04:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '1959'	(b) (4), (b) (6) System	24 Aug 2020 14:52:09

FDA-CBER-2022-1614-0647077

US3232048
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:04:06
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:52:09

FDA-CBER-2022-1614-0647078

US3232048
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:04:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:52:09

FDA-CBER-2022-1614-0647079

US3232048
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:53:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:53:32
Data point term sent to Coder	System	24 Aug 2020 14:52:47
User entered 'high blood pressure'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:29

FDA-CBER-2022-1614-0647080

US3232048
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:04:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '18 Dec 2013'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:29

FDA-CBER-2022-1614-0647081

US3232048
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:29

FDA-CBER-2022-1614-0647082

US3232048
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:04:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:29

FDA-CBER-2022-1614-0647083

US3232048
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:04:06
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:29

FDA-CBER-2022-1614-0647084

US3232048
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:04:06
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:52:29

FDA-CBER-2022-1614-0647085

US3232048
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:04:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Dec 2013'	(b) (4), (b) (6) System	24 Aug 2020 14:52:29

FDA-CBER-2022-1614-0647086

US3232048
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:04:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2013'	(b) (4), (b) (6) System	24 Aug 2020 14:52:29

FDA-CBER-2022-1614-0647087

US3232048
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:04:06
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:52:29

FDA-CBER-2022-1614-0647088

US3232048
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:04:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:52:29

FDA-CBER-2022-1614-0647089

US3232048
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Heart rate and pulse investigations, PT: Heart rate irregular, LLT: Heartbeats irregular - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:54:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:54:38
Data point term sent to Coder	System	24 Aug 2020 14:53:50
User entered 'irregular heart beat'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:16

FDA-CBER-2022-1614-0647090

US3232048
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:04:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '16 May 2019'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:16

FDA-CBER-2022-1614-0647091

US3232048
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:16

FDA-CBER-2022-1614-0647092

US3232048
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:04:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:16

FDA-CBER-2022-1614-0647093

US3232048
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:04:06
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '16 May 2019'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:16

FDA-CBER-2022-1614-0647094

US3232048
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:04:06
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:16

FDA-CBER-2022-1614-0647095

US3232048
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:04:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'May 2019'	(b) (4), (b) (6) System	24 Aug 2020 14:53:16

FDA-CBER-2022-1614-0647096

US3232048
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:04:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2019'	(b) (4), (b) (6) System	24 Aug 2020 14:53:16

FDA-CBER-2022-1614-0647097

US3232048
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:04:06
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'May 2019'	(b) (4), (b) (6) System	24 Aug 2020 14:53:16

FDA-CBER-2022-1614-0647098

US3232048
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:04:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2019'	(b) (4), (b) (6) System	24 Aug 2020 14:53:16

FDA-CBER-2022-1614-0647099

US3232048
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:54:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:54:36
Data point term sent to Coder	System	24 Aug 2020 14:53:50
User entered 'atrial fibrillation'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:48

FDA-CBER-2022-1614-0647100

US3232048
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:04:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '19 Dec 2013'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:48

FDA-CBER-2022-1614-0647101

US3232048
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:48

FDA-CBER-2022-1614-0647102

US3232048
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:04:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:48

FDA-CBER-2022-1614-0647103

US3232048
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:04:06
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'un UNK 2014'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:48

FDA-CBER-2022-1614-0647104

US3232048
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:04:06
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:53:48

FDA-CBER-2022-1614-0647105

US3232048
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:04:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Dec 2013'	(b) (4), (b) (6) System	24 Aug 2020 14:53:48

FDA-CBER-2022-1614-0647106

US3232048
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:04:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2013'	(b) (4), (b) (6) System	24 Aug 2020 14:53:48

FDA-CBER-2022-1614-0647107

US3232048
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:04:06
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Jan 2014'	(b) (4), (b) (6) System	24 Aug 2020 14:53:48

FDA-CBER-2022-1614-0647108

US3232048
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:04:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2014'	(b) (4), (b) (6) System	24 Aug 2020 14:53:48

FDA-CBER-2022-1614-0647109

US3232048
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:55:40
Data point term sent to Coder	System	24 Aug 2020 14:54:52
User entered 'inguinal hernia'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:04

FDA-CBER-2022-1614-0647110

US3232048
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:04:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'un UNK 2013'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:04

FDA-CBER-2022-1614-0647111

US3232048
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:04

FDA-CBER-2022-1614-0647112

US3232048
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:04:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:04

FDA-CBER-2022-1614-0647113

US3232048
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:04:06
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'un UNK 2013'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:04

FDA-CBER-2022-1614-0647114

US3232048
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:04:06
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:04

FDA-CBER-2022-1614-0647115

US3232048
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:04:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
	(b) (4), (b) (6)	
User entered 'Jan 2013'	System	24 Aug 2020 14:54:04

FDA-CBER-2022-1614-0647116

US3232048
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:04:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2013'	(b) (4), (b) (6) System	24 Aug 2020 14:54:04

FDA-CBER-2022-1614-0647117

US3232048
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:04:06
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Jan 2013'	(b) (4), (b) (6) System	24 Aug 2020 14:54:04

FDA-CBER-2022-1614-0647118

US3232048
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:04:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2013'	(b) (4), (b) (6) System	24 Aug 2020 14:54:04

FDA-CBER-2022-1614-0647119

US3232048
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
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: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:55:40
Data point term sent to Coder	System	24 Aug 2020 14:54:51
User entered 'GERD'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:16

FDA-CBER-2022-1614-0647120

US3232048
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:04:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '24 Sep 2019'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:16

FDA-CBER-2022-1614-0647121

US3232048
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:16

FDA-CBER-2022-1614-0647122

US3232048
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:04:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:16

FDA-CBER-2022-1614-0647123

US3232048
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:04:06
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:16

FDA-CBER-2022-1614-0647124

US3232048
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:04:06
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:16

FDA-CBER-2022-1614-0647125

US3232048
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:04:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Sep 2019'	(b) (4), (b) (6) System	24 Aug 2020 14:54:16

FDA-CBER-2022-1614-0647126

US3232048
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:04:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
	(b) (4), (b) (6)	
User entered '2019'	System	24 Aug 2020 14:54:16

FDA-CBER-2022-1614-0647127

US3232048
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:04:06
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:54:16

FDA-CBER-2022-1614-0647128

US3232048
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:04:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:54:16

FDA-CBER-2022-1614-0647129

US3232048
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:55:40
Data point term sent to Coder	System	24 Aug 2020 14:54:52
User entered 'Erectile dysfunction'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:33

FDA-CBER-2022-1614-0647130

US3232048
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:04:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'un UNK 2015'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:33

FDA-CBER-2022-1614-0647131

US3232048
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:33

FDA-CBER-2022-1614-0647132

US3232048
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:04:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:33

FDA-CBER-2022-1614-0647133

US3232048
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:04:06
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:33

FDA-CBER-2022-1614-0647134

US3232048
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:04:06
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:33

FDA-CBER-2022-1614-0647135

US3232048
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:04:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Jan 2015'	(b) (4), (b) (6) System	24 Aug 2020 14:54:33

FDA-CBER-2022-1614-0647136

US3232048
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:04:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2015'	(b) (4), (b) (6) System	24 Aug 2020 14:54:33

FDA-CBER-2022-1614-0647137

US3232048
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:04:06
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:54:33

FDA-CBER-2022-1614-0647138

US3232048
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:04:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:54:33

FDA-CBER-2022-1614-0647139

US3232048
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:55:40
Data point term sent to Coder	System	24 Aug 2020 14:54:53
User entered 'BPH'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:50

FDA-CBER-2022-1614-0647140

US3232048
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:04:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '19 Dec 2013'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:50

FDA-CBER-2022-1614-0647141

US3232048
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:50

FDA-CBER-2022-1614-0647142

US3232048
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:04:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:50

FDA-CBER-2022-1614-0647143

US3232048
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:04:06
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '23 Nov 2015'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:50

FDA-CBER-2022-1614-0647144

US3232048
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:04:06
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:54:50

FDA-CBER-2022-1614-0647145

US3232048
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:04:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Dec 2013'	(b) (4), (b) (6) System	24 Aug 2020 14:54:50

FDA-CBER-2022-1614-0647146

US3232048
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:04:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2013'	(b) (4), (b) (6) System	24 Aug 2020 14:54:50

FDA-CBER-2022-1614-0647147

US3232048
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:04:06
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Nov 2015'	(b) (4), (b) (6) System	24 Aug 2020 14:54:50

FDA-CBER-2022-1614-0647148

US3232048
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:04:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2015'	(b) (4), (b) (6) System	24 Aug 2020 14:54:50

FDA-CBER-2022-1614-0647149

US3232048
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as SOC: Nervous system disorders, HLGT: Neuromuscular disorders, HLT: Motor neurone diseases, PT: Amyotrophic lateral sclerosis, LLT: Amyotrophic lateral sclerosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 13:41:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 13:41:59
Data point term sent to Coder	System	13 Jan 2021 13:41:22
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 13:40:40
User entered 'Amyotrophic Lateral Sclerosis' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 13:40:40
User coded data point as SOC: Nervous system disorders, HLGT: Neuromuscular disorders, HLT: Motor neurone diseases, PT: Amyotrophic lateral sclerosis, LLT: ALS - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:56:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:56:35
Data point term sent to Coder	System	24 Aug 2020 14:55:53
User entered 'ALS'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:09

FDA-CBER-2022-1614-0647150

US3232048
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:04:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '2 Dec 2019'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:09

FDA-CBER-2022-1614-0647151

US3232048
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:09

FDA-CBER-2022-1614-0647152

US3232048
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:04:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:09

FDA-CBER-2022-1614-0647153

US3232048
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:04:06
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:09

FDA-CBER-2022-1614-0647154

US3232048
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:04:06
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:09

FDA-CBER-2022-1614-0647155

US3232048
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:04:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Dec 2019'	(b) (4), (b) (6) System	24 Aug 2020 14:55:09

FDA-CBER-2022-1614-0647156

US3232048
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:04:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2019'	(b) (4), (b) (6) System	24 Aug 2020 14:55:09

FDA-CBER-2022-1614-0647157

US3232048
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:04:06
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:55:09

FDA-CBER-2022-1614-0647158

US3232048
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:04:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:55:09

FDA-CBER-2022-1614-0647159

US3232048
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
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)	24 Aug 2020 14:56:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:56:34
Data point term sent to Coder	System	24 Aug 2020 14:55:54
User entered 'Insomnia'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:24

FDA-CBER-2022-1614-0647160

US3232048
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:04:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '4 Feb 2020'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:24

FDA-CBER-2022-1614-0647161

US3232048
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:24

FDA-CBER-2022-1614-0647162

US3232048
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:04:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:24

FDA-CBER-2022-1614-0647163

US3232048
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:04:06
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:24

FDA-CBER-2022-1614-0647164

US3232048
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:04:06
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:24

FDA-CBER-2022-1614-0647165

US3232048
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:04:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'Feb 2020'	(b) (4), (b) (6) System	24 Aug 2020 14:55:24

FDA-CBER-2022-1614-0647166

US3232048
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:04:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2020'	(b) (4), (b) (6) System	24 Aug 2020 14:55:24

FDA-CBER-2022-1614-0647167

US3232048
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:04:06
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:55:24

FDA-CBER-2022-1614-0647168

US3232048
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:04:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:55:24

FDA-CBER-2022-1614-0647169

US3232048
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:04:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as SOC: Nervous system disorders, HLGT: Mental impairment disorders, HLT: Memory loss (excl dementia), PT: Memory impairment, LLT: Memory impairment - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:48:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:48:36
Data point term sent to Coder	System	24 Aug 2020 14:55:58
User entered 'memory changes'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:46

FDA-CBER-2022-1614-0647170

US3232048
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:04:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'un UNK 2017'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:46

FDA-CBER-2022-1614-0647171

US3232048
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:46

FDA-CBER-2022-1614-0647172

US3232048
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:04:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:46

FDA-CBER-2022-1614-0647173

US3232048
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:04:06
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:46

FDA-CBER-2022-1614-0647174

US3232048
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:04:06
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:55:46

FDA-CBER-2022-1614-0647175

US3232048
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:04:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
	(b) (4), (b) (6)	
User entered 'Jan 2017'	System	24 Aug 2020 14:55:46

FDA-CBER-2022-1614-0647176

US3232048
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:04:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '2017'	(b) (4), (b) (6) System	24 Aug 2020 14:55:46

FDA-CBER-2022-1614-0647177

US3232048
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:04:06
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:55:46

FDA-CBER-2022-1614-0647178

US3232048
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:04:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 14:55:46

FDA-CBER-2022-1614-0647179

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:59

FDA-CBER-2022-1614-0647180

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '14 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:59

FDA-CBER-2022-1614-0647181

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '9:58'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:59

FDA-CBER-2022-1614-0647182

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '14 Aug 2020 9:58'	(b) (4), (b) (6) System	21 Aug 2020 20:08:59

FDA-CBER-2022-1614-0647183

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 19:05:48
User entered '160' cm	(b) (4) Jerrica Sullivan (b) (4)	21 Aug 2020 20:08:59
DataPoint set to visible.	(b) (4) System	21 Aug 2020 16:27:09

FDA-CBER-2022-1614-0647184

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 19:05:48
User entered '67.5' kg	Jerrica Sullivan (b) (4)	21 Aug 2020 20:08:59
DataPoint set to visible.	(b) (4) System	21 Aug 2020 16:27:09

FDA-CBER-2022-1614-0647185

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
	(b) (4), (b) (6)	
Amendment Manager: User entered '26.36719'	System	16 Sep 2020 23:56:55
User entered '26.4'	System	21 Aug 2020 20:08:59
DataPoint set to visible.	System	21 Aug 2020 16:27:09

FDA-CBER-2022-1614-0647186

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	21 Aug 2020 20:08:59
DataPoint set to visible.	System	21 Aug 2020 16:27:09

FDA-CBER-2022-1614-0647187

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '97.5' F reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:54:05
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:59

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (Oral)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:54:05
User entered 'Other (Other)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:59

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:54:05
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:59

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '78' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:54:05
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:59

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 20:08:59

FDA-CBER-2022-1614-0647192

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '18' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:54:05
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:59

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 20:08:59

FDA-CBER-2022-1614-0647194

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '111' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:54:05
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:59

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 20:08:59

FDA-CBER-2022-1614-0647196

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '78' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:54:05
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:08:59

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 20:08:59

FDA-CBER-2022-1614-0647198

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52

FDA-CBER-2022-1614-0647199

US3232048
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52

FDA-CBER-2022-1614-0647200

US3232048
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:04:06
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:09:11

FDA-CBER-2022-1614-0647201

US3232048
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:04:06
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Sep 2020 10:34:44
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 21:51:00
User entered '14 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:09:11

FDA-CBER-2022-1614-0647202

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647204

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647205

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647206

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647207

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647209

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647210

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 19:05:48
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647211

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647212

US3232048

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647214

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647215

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647216

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647217

US3232048

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

US3232048

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647221

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

FDA-CBER-2022-1614-0647222

US3232048
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:04:06
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 19:05:48
User entered 'resident in a community with ongoing person to person transmission'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:03

US3232048
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:15

FDA-CBER-2022-1614-0647224

US3232048
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	28 Aug 2020 21:51:00
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered by data change (Site from System).	System	28 Aug 2020 21:51:00
User entered '21 Aug 2020' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:51:00
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	21 Aug 2020 20:10:15
User entered '14 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:15

FDA-CBER-2022-1614-0647225

US3232048
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Clinic (Clinic)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:15

FDA-CBER-2022-1614-0647226

US3232048
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'VISIT1'	(b) (4), (b) (6) System	21 Aug 2020 20:10:15

FDA-CBER-2022-1614-0647227

US3232048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:06

What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 21:51:00
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	28 Aug 2020 21:51:00
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Aug 2020 20:10:15
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 15:24:28

US3232048
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:04:06
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '187263'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 15:24:28

FDA-CBER-2022-1614-0647229

US3232048
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:04:06
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 15:24:28

FDA-CBER-2022-1614-0647230

US3232048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 19:15:05

US3232048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 19:15:05

US3232048
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:04:06
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 19:15:05

FDA-CBER-2022-1614-0647233

US3232048
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:04:06
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 19:15:05

FDA-CBER-2022-1614-0647234

US3232048
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:04:06
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 19:15:05

FDA-CBER-2022-1614-0647235

US3232048
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:04:06
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 19:05:48
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4)	01 Dec 2020 19:27:42
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:20:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:15:03

FDA-CBER-2022-1614-0647236

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:04:06
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647237

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:04:06
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647238

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:04:06
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647239

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:04:06
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647240

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User accepted default value 'Pre-Dose (PREDOSE)'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647241

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 21:55:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 21:55:17
User entered 'No (N)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:55:17
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 21:55:09
User entered empty; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:55:09
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 21:55:09
User entered empty; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:55:09
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 21:51:00
User entered '14 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:55:09
User entered '9:58'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
	(b) (4), (b) (6)	
User entered empty.	System	28 Aug 2020 21:55:09
User entered '14 Aug 2020 9:58'	System	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647245

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:55:09
User entered '97.5' F	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647246

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:55:09
User entered 'Oral (Oral)'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647248

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:55:09
User entered '78'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647249

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	System	28 Aug 2020 21:55:09
User entered 'bpm'	System	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647250

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:55:09
User entered '18'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647251

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
	(b) (4), (b) (6)	
User entered empty.	System	28 Aug 2020 21:55:09
User entered 'breaths/min'	System	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647252

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:55:09
User entered '111'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647253

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
	(b) (4), (b) (6)	
User entered empty.	System	28 Aug 2020 21:55:09
User entered 'mmHg'	System	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647254

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:55:09
User entered '78'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
	(b) (4), (b) (6)	
User entered empty.	System	28 Aug 2020 21:55:09
User entered 'mmHg'	System	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647256

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:04:06
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647257

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:04:06
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered missing code ND - Not Done.	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647258

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User accepted default value 'Post-Dose (POSTDOSE)'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647259

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647260

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 21:51:00
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 19:06:46
User entered '21 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647261

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '11:52'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647262

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '21 Aug 2020 11:52'	(b) (4), (b) (6) System	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647263

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '97.0' F	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647264

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Other (Other)'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647265

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 19:05:48
User entered 'TEMPORAL'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647266

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '81'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647267

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'bpm'	(b) (4), (b) (6) System	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647268

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '18'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647269

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'breaths/min'	(b) (4), (b) (6) System	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647270

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '119'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'mmHg'	(b) (4), (b) (6) System	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647272

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '82'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:06:46

US3232048
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'mmHg'	(b) (4), (b) (6) System	28 Aug 2020 19:06:46

FDA-CBER-2022-1614-0647274

US3232048
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 16:04:06
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:25

FDA-CBER-2022-1614-0647275

US3232048
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 16:04:06
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:10:25

FDA-CBER-2022-1614-0647276

US3232048
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647277

US3232048
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647278

US3232048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 16:28:01

US3232048
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647280

US3232048
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 21:51:00
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	28 Aug 2020 21:51:00
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	21 Aug 2020 20:10:15
User entered '21 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647281

US3232048
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '11:00'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647282

US3232048
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '21 Aug 2020 11:00'	(b) (4), (b) (6) System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647283

US3232048
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Right Arm (RIGHT ARM)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647284

US3232048
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'ONCE'	(b) (4), (b) (6) System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647285

US3232048
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647286

US3232048
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:11:16

FDA-CBER-2022-1614-0647287

US3232048
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 21:51:00
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	28 Aug 2020 21:51:00
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Aug 2020 20:11:16
User entered '21 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:11:16

FDA-CBER-2022-1614-0647288

US3232048
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '11:18'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:11:16

FDA-CBER-2022-1614-0647289

US3232048
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '21 Aug 2020 11:18'	(b) (4), (b) (6) System	21 Aug 2020 20:11:16

FDA-CBER-2022-1614-0647290

US3232048
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 16:04:06
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 21:51:00
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	28 Aug 2020 21:51:00
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 19:07:25
User entered '21 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:07:25

US3232048
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:04:06
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:07:25

FDA-CBER-2022-1614-0647292

US3232048
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:04:06
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:07:25

FDA-CBER-2022-1614-0647293

US3232048
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:04:06
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '10:30'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:07:25

FDA-CBER-2022-1614-0647294

US3232048
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:04:06
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '21 Aug 2020 10:30'	(b) (4), (b) (6) System	28 Aug 2020 19:07:25

FDA-CBER-2022-1614-0647295

US3232048
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:04:06
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:07:25

FDA-CBER-2022-1614-0647296

US3232048
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:04:06
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:07:25

FDA-CBER-2022-1614-0647297

US3232048
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:04:06
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	28 Aug 2020 19:07:25

FDA-CBER-2022-1614-0647298

US3232048
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:04:06
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered empty.	(b) (4), (b) (6) System	28 Aug 2020 19:07:25

FDA-CBER-2022-1614-0647299

US3232048
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 22:39:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:11:50

FDA-CBER-2022-1614-0647300

US3232048
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:52
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 20:11:50

FDA-CBER-2022-1614-0647301

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647302

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:37:40', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd17572bb-70d3-427a-ac86-420f04561617'	System	21 Aug 2020 16:38:30
User entered 'Yes (Y)'	System	21 Aug 2020 16:38:30

FDA-CBER-2022-1614-0647303

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:38:16', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd17572bb-70d3-427a-ac86-420f04561617'	System	21 Aug 2020 16:38:30
User entered '97.0'	System	21 Aug 2020 16:38:30

FDA-CBER-2022-1614-0647304

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:38:19', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd17572bb-70d3-427a-ac86-420f04561617'	System	21 Aug 2020 16:38:30
User entered 'No (N)'	System	21 Aug 2020 16:38:30

FDA-CBER-2022-1614-0647305

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:38:26', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd17572bb-70d3-427a-ac86-420f04561617'	System	21 Aug 2020 16:38:30
User entered '21 Aug 2020 11:38'	System	21 Aug 2020 16:38:30

FDA-CBER-2022-1614-0647306

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Aug 2020 11:20'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647307

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Aug 2020 13:50'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647308

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647309

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:41:18', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '1bcdf8c6-8e7c-40db-b15d-45d8ec7bf2fa'	System	22 Aug 2020 00:42:51
User entered 'Yes (Y)'	System	22 Aug 2020 00:42:51

FDA-CBER-2022-1614-0647310

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:42:21', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '1bcdf8c6-8e7c-40db-b15d-45d8ec7bf2fa'	System	22 Aug 2020 00:42:51
User entered '98.2'	System	22 Aug 2020 00:42:51

FDA-CBER-2022-1614-0647311

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:42:41', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '1bcdf8c6-8e7c-40db-b15d-45d8ec7bf2fa'	System	22 Aug 2020 00:42:51
User entered 'No (N)'	System	22 Aug 2020 00:42:51

FDA-CBER-2022-1614-0647312

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:42:47', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '1bcdf8c6-8e7c-40db-b15d-45d8ec7bf2fa'	System	22 Aug 2020 00:42:51
User entered '21 Aug 2020 19:42'	System	22 Aug 2020 00:42:51

FDA-CBER-2022-1614-0647313

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Aug 2020 14:45'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647314

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647315

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 2'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647316

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:51:15', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '31d686ee-baa0-437b-b527-5e63ab8e9de4'	System	23 Aug 2020 00:51:34
User entered 'Yes (Y)'	System	23 Aug 2020 00:51:34

FDA-CBER-2022-1614-0647317

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:51:20', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '31d686ee-baa0-437b-b527-5e63ab8e9de4'	System	23 Aug 2020 00:51:34
User entered '97.5'	System	23 Aug 2020 00:51:34

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:51:26', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '31d686ee-baa0-437b-b527-5e63ab8e9de4'	System	23 Aug 2020 00:51:34
User entered 'No (N)'	System	23 Aug 2020 00:51:34

FDA-CBER-2022-1614-0647319

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:51:31', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '31d686ee-baa0-437b-b527-5e63ab8e9de4'	System	23 Aug 2020 00:51:34
User entered '22 Aug 2020 19:51'	System	23 Aug 2020 00:51:34

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647321

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647322

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 3'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647323

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:45:57', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e317a7b9-23dc-43a7-98c8-669eff7faeeb'	System	24 Aug 2020 00:46:18
User entered 'Yes (Y)'	System	24 Aug 2020 00:46:18

FDA-CBER-2022-1614-0647324

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:04', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e317a7b9-23dc-43a7-98c8-669eff7faeeb'	System	24 Aug 2020 00:46:18
User entered '97.2'	System	24 Aug 2020 00:46:18

FDA-CBER-2022-1614-0647325

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:09', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e317a7b9-23dc-43a7-98c8-669eff7faeeb'	System	24 Aug 2020 00:46:18
User entered 'No (N)'	System	24 Aug 2020 00:46:18

FDA-CBER-2022-1614-0647326

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:13', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e317a7b9-23dc-43a7-98c8-669eff7faeeb'	System	24 Aug 2020 00:46:18
User entered '23 Aug 2020 19:46'	System	24 Aug 2020 00:46:18

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647328

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647329

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 4'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647330

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:00:29', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '98387d09-4cc9-4ae0-8495-0339b9685e32'	System	25 Aug 2020 01:00:45
User entered 'Yes (Y)'	System	25 Aug 2020 01:00:45

FDA-CBER-2022-1614-0647331

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:00:36', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '98387d09-4cc9-4ae0-8495-0339b9685e32'	System	25 Aug 2020 01:00:45
User entered '97.9'	System	25 Aug 2020 01:00:45

FDA-CBER-2022-1614-0647332

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:00:40', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '98387d09-4cc9-4ae0-8495-0339b9685e32'	System	25 Aug 2020 01:00:45
User entered 'No (N)'	System	25 Aug 2020 01:00:45

FDA-CBER-2022-1614-0647333

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:00:44', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '98387d09-4cc9-4ae0-8495-0339b9685e32'	System	25 Aug 2020 01:00:45
User entered '24 Aug 2020 20:00'	System	25 Aug 2020 01:00:45

FDA-CBER-2022-1614-0647334

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647335

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647336

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 5'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647337

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:13:46', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3d7ef312-4fdb-4e84-902e-6048687cdd39'	System	26 Aug 2020 01:14:29
User entered 'Yes (Y)'	System	26 Aug 2020 01:14:29

FDA-CBER-2022-1614-0647338

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:19', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3d7ef312-4fdb-4e84-902e-6048687cdd39'	System	26 Aug 2020 01:14:29
User entered '96.5'	System	26 Aug 2020 01:14:29

FDA-CBER-2022-1614-0647339

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:23', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3d7ef312-4fdb-4e84-902e-6048687cdd39'	System	26 Aug 2020 01:14:29
User entered 'No (N)'	System	26 Aug 2020 01:14:29

FDA-CBER-2022-1614-0647340

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:27', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3d7ef312-4fdb-4e84-902e-6048687cdd39'	System	26 Aug 2020 01:14:29
User entered '25 Aug 2020 20:14'	System	26 Aug 2020 01:14:29

FDA-CBER-2022-1614-0647341

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647342

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647343

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 6'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647344

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:12:07', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ee7d5a8f-cb8e-4bc6-a0ed-5d4352eb4930'	System	27 Aug 2020 01:12:46
User entered 'Yes (Y)'	System	27 Aug 2020 01:12:46

FDA-CBER-2022-1614-0647345

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:12:35', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ee7d5a8f-cb8e-4bc6-a0ed-5d4352eb4930'	System	27 Aug 2020 01:12:46
User entered '98.5'	System	27 Aug 2020 01:12:46

FDA-CBER-2022-1614-0647346

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:12:38', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ee7d5a8f-cb8e-4bc6-a0ed-5d4352eb4930'	System	27 Aug 2020 01:12:46
User entered 'No (N)'	System	27 Aug 2020 01:12:46

FDA-CBER-2022-1614-0647347

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:12:44', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ee7d5a8f-cb8e-4bc6-a0ed-5d4352eb4930'	System	27 Aug 2020 01:12:46
User entered '26 Aug 2020 20:12'	System	27 Aug 2020 01:12:46

FDA-CBER-2022-1614-0647348

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647349

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647350

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 7'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647351

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:22:47', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'cf95a290-3be1-4f6e-9521-6de2b51c4361'	System	28 Aug 2020 01:23:07
User entered 'Yes (Y)'	System	28 Aug 2020 01:23:07

FDA-CBER-2022-1614-0647352

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:22:57', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'cf95a290-3be1-4f6e-9521-6de2b51c4361'	System	28 Aug 2020 01:23:07
User entered '97.9'	System	28 Aug 2020 01:23:07

FDA-CBER-2022-1614-0647353

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:01', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'cf95a290-3be1-4f6e-9521-6de2b51c4361'	System	28 Aug 2020 01:23:07
User entered 'No (N)'	System	28 Aug 2020 01:23:07

FDA-CBER-2022-1614-0647354

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:04', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'cf95a290-3be1-4f6e-9521-6de2b51c4361'	System	28 Aug 2020 01:23:07
User entered '27 Aug 2020 20:23'	System	28 Aug 2020 01:23:07

FDA-CBER-2022-1614-0647355

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647356

US3232048
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647357

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647358

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:38:42', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'df267c22-fa08-4455-be8a-d92bb2374088'	System	21 Aug 2020 16:39:44
User entered 'None (1)'	System	21 Aug 2020 16:39:44

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:38:58', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'df267c22-fa08-4455-be8a-d92bb2374088'	System	21 Aug 2020 16:39:44
User entered 'No (N)'	System	21 Aug 2020 16:39:44

FDA-CBER-2022-1614-0647360

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:39:14', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'df267c22-fa08-4455-be8a-d92bb2374088'	System	21 Aug 2020 16:39:44
User entered 'No (N)'	System	21 Aug 2020 16:39:44

FDA-CBER-2022-1614-0647361

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:39:32', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'df267c22-fa08-4455-be8a-d92bb2374088'	System	21 Aug 2020 16:39:44
User entered 'None (1)'	System	21 Aug 2020 16:39:44

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:39:35', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'df267c22-fa08-4455-be8a-d92bb2374088'	System	21 Aug 2020 16:39:44
User entered '21 Aug 2020 11:39'	System	21 Aug 2020 16:39:44

FDA-CBER-2022-1614-0647363

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Aug 2020 11:20'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647364

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Aug 2020 13:50'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647365

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647366

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:43:06', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '56260f97-4fdc-4c95-b730-dec7b8bae9cb'	System	22 Aug 2020 00:43:52
User entered 'None (1)'	System	22 Aug 2020 00:43:52

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:43:36', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '56260f97-4fdc-4c95-b730-dec7b8bae9cb'	System	22 Aug 2020 00:43:52
User entered 'No (N)'	System	22 Aug 2020 00:43:52

FDA-CBER-2022-1614-0647368

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:43:39', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '56260f97-4fdc-4c95-b730-dec7b8bae9cb'	System	22 Aug 2020 00:43:52
User entered 'No (N)'	System	22 Aug 2020 00:43:52

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:43:47', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '56260f97-4fdc-4c95-b730-dec7b8bae9cb'	System	22 Aug 2020 00:43:52
User entered 'None (1)'	System	22 Aug 2020 00:43:52

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:43:51', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '56260f97-4fdc-4c95-b730-dec7b8bae9cb'	System	22 Aug 2020 00:43:52
User entered '21 Aug 2020 19:43'	System	22 Aug 2020 00:43:52

FDA-CBER-2022-1614-0647371

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Aug 2020 14:45'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647372

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647373

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 2'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647374

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:51:39', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '70836b96-a2ae-43ed-b938-56c84ab21995'	System	23 Aug 2020 00:51:56
User entered 'None (1)'	System	23 Aug 2020 00:51:56

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:51:43', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '70836b96-a2ae-43ed-b938-56c84ab21995'	System	23 Aug 2020 00:51:56
User entered 'No (N)'	System	23 Aug 2020 00:51:56

FDA-CBER-2022-1614-0647376

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:51:46', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '70836b96-a2ae-43ed-b938-56c84ab21995'	System	23 Aug 2020 00:51:56
User entered 'No (N)'	System	23 Aug 2020 00:51:56

FDA-CBER-2022-1614-0647377

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:51:52', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '70836b96-a2ae-43ed-b938-56c84ab21995'	System	23 Aug 2020 00:51:56
User entered 'None (1)'	System	23 Aug 2020 00:51:56

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:51:55', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '70836b96-a2ae-43ed-b938-56c84ab21995'	System	23 Aug 2020 00:51:56
User entered '22 Aug 2020 19:51'	System	23 Aug 2020 00:51:56

FDA-CBER-2022-1614-0647379

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647380

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647381

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 3'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647382

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:19', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4aa71a18-b09d-4193-8126-e6656b142129'	System	24 Aug 2020 00:46:34
User entered 'None (1)'	System	24 Aug 2020 00:46:34

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:23', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4aa71a18-b09d-4193-8126-e6656b142129'	System	24 Aug 2020 00:46:34
User entered 'No (N)'	System	24 Aug 2020 00:46:34

FDA-CBER-2022-1614-0647384

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:26', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4aa71a18-b09d-4193-8126-e6656b142129'	System	24 Aug 2020 00:46:34
User entered 'No (N)'	System	24 Aug 2020 00:46:34

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:29', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4aa71a18-b09d-4193-8126-e6656b142129'	System	24 Aug 2020 00:46:34
User entered 'None (1)'	System	24 Aug 2020 00:46:34

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:32', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4aa71a18-b09d-4193-8126-e6656b142129'	System	24 Aug 2020 00:46:34
User entered '23 Aug 2020 19:46'	System	24 Aug 2020 00:46:34

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647388

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647389

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 4'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647390

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:00:49', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4df37a94-b821-4f78-94ee-8bf6f577437e'	System	25 Aug 2020 01:01:10
User entered 'None (1)'	System	25 Aug 2020 01:01:10

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:00:52', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4df37a94-b821-4f78-94ee-8bf6f577437e'	System	25 Aug 2020 01:01:10
User entered 'No (N)'	System	25 Aug 2020 01:01:10

FDA-CBER-2022-1614-0647392

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:00:56', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4df37a94-b821-4f78-94ee-8bf6f577437e'	System	25 Aug 2020 01:01:10
User entered 'No (N)'	System	25 Aug 2020 01:01:10

FDA-CBER-2022-1614-0647393

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:01:03', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4df37a94-b821-4f78-94ee-8bf6f577437e'	System	25 Aug 2020 01:01:10
User entered 'None (1)'	System	25 Aug 2020 01:01:10

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:01:06', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4df37a94-b821-4f78-94ee-8bf6f577437e'	System	25 Aug 2020 01:01:10
User entered '24 Aug 2020 20:01'	System	25 Aug 2020 01:01:10

FDA-CBER-2022-1614-0647395

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647396

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647397

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 5'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647398

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:32', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '11f47e75-2795-4e40-b4c0-531710f277f7'	System	26 Aug 2020 01:14:48
User entered 'None (1)'	System	26 Aug 2020 01:14:48

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:35', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '11f47e75-2795-4e40-b4c0-531710f277f7'	System	26 Aug 2020 01:14:48
User entered 'No (N)'	System	26 Aug 2020 01:14:48

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:40', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '11f47e75-2795-4e40-b4c0-531710f277f7'	System	26 Aug 2020 01:14:48
User entered 'No (N)'	System	26 Aug 2020 01:14:48

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:43', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '11f47e75-2795-4e40-b4c0-531710f277f7'	System	26 Aug 2020 01:14:48
User entered 'None (1)'	System	26 Aug 2020 01:14:48

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:46', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '11f47e75-2795-4e40-b4c0-531710f277f7'	System	26 Aug 2020 01:14:48
User entered '25 Aug 2020 20:14'	System	26 Aug 2020 01:14:48

FDA-CBER-2022-1614-0647403

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647404

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647405

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 6'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647406

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:12:49', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c9894a8c-8cbe-4ee5-bc8f-13872334404b'	System	27 Aug 2020 01:13:06
User entered 'None (1)'	System	27 Aug 2020 01:13:06

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:12:52', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c9894a8c-8cbe-4ee5-bc8f-13872334404b'	System	27 Aug 2020 01:13:06
User entered 'No (N)'	System	27 Aug 2020 01:13:06

FDA-CBER-2022-1614-0647408

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:12:55', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c9894a8c-8cbe-4ee5-bc8f-13872334404b'	System	27 Aug 2020 01:13:06
User entered 'No (N)'	System	27 Aug 2020 01:13:06

FDA-CBER-2022-1614-0647409

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:12:57', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c9894a8c-8cbe-4ee5-bc8f-13872334404b'	System	27 Aug 2020 01:13:06
User entered 'None (1)'	System	27 Aug 2020 01:13:06

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:13:02', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c9894a8c-8cbe-4ee5-bc8f-13872334404b'	System	27 Aug 2020 01:13:06
User entered '26 Aug 2020 20:13'	System	27 Aug 2020 01:13:06

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647412

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647413

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 7'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647414

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:08', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b5852976-ad06-4059-b0db-b877452717b8'	System	28 Aug 2020 01:23:24
User entered 'None (1)'	System	28 Aug 2020 01:23:24

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:11', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b5852976-ad06-4059-b0db-b877452717b8'	System	28 Aug 2020 01:23:24
User entered 'No (N)'	System	28 Aug 2020 01:23:24

FDA-CBER-2022-1614-0647416

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:15', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b5852976-ad06-4059-b0db-b877452717b8'	System	28 Aug 2020 01:23:24
User entered 'No (N)'	System	28 Aug 2020 01:23:24

FDA-CBER-2022-1614-0647417

US3232048

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:19', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b5852976-ad06-4059-b0db-b877452717b8'	System	28 Aug 2020 01:23:24
User entered 'None (1)'	System	28 Aug 2020 01:23:24

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:21', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b5852976-ad06-4059-b0db-b877452717b8'	System	28 Aug 2020 01:23:24
User entered '27 Aug 2020 20:23'	System	28 Aug 2020 01:23:24

FDA-CBER-2022-1614-0647419

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647420

US3232048
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647421

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647422

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:39:45', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b592439c-e4d7-4f8a-88e7-8c7bf30bc104'	System	21 Aug 2020 16:40:16
User entered 'None (0)'	System	21 Aug 2020 16:40:16

FDA-CBER-2022-1614-0647423

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:39:49', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b592439c-e4d7-4f8a-88e7-8c7bf30bc104'	System	21 Aug 2020 16:40:16
User entered 'None (0)'	System	21 Aug 2020 16:40:16

FDA-CBER-2022-1614-0647424

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:39:53', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b592439c-e4d7-4f8a-88e7-8c7bf30bc104'	System	21 Aug 2020 16:40:16
User entered 'None (0)'	System	21 Aug 2020 16:40:16

FDA-CBER-2022-1614-0647425

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:39:57', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b592439c-e4d7-4f8a-88e7-8c7bf30bc104'	System	21 Aug 2020 16:40:16
User entered 'None (0)'	System	21 Aug 2020 16:40:16

FDA-CBER-2022-1614-0647426

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:40:00', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b592439c-e4d7-4f8a-88e7-8c7bf30bc104'	System	21 Aug 2020 16:40:16
User entered 'None (0)'	System	21 Aug 2020 16:40:16

FDA-CBER-2022-1614-0647427

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:40:04', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b592439c-e4d7-4f8a-88e7-8c7bf30bc104'	System	21 Aug 2020 16:40:16
User entered 'None (0)'	System	21 Aug 2020 16:40:16

FDA-CBER-2022-1614-0647428

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:40:07', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b592439c-e4d7-4f8a-88e7-8c7bf30bc104'	System	21 Aug 2020 16:40:16
User entered 'No (N)'	System	21 Aug 2020 16:40:16

FDA-CBER-2022-1614-0647429

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T11:40:13', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b592439c-e4d7-4f8a-88e7-8c7bf30bc104'	System	21 Aug 2020 16:40:16
User entered '21 Aug 2020 11:40'	System	21 Aug 2020 16:40:16

FDA-CBER-2022-1614-0647430

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Aug 2020 11:20'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647431

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Aug 2020 13:50'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647432

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647433

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:44:02', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '7084d041-7ae7-4d69-bbd2-9e390fbce465'	System	22 Aug 2020 00:44:59
User entered 'None (0)'	System	22 Aug 2020 00:44:59

FDA-CBER-2022-1614-0647434

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:44:08', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '7084d041-7ae7-4d69-bbd2-9e390fbce465'	System	22 Aug 2020 00:44:59
User entered 'None (0)'	System	22 Aug 2020 00:44:59

FDA-CBER-2022-1614-0647435

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:44:38', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '7084d041-7ae7-4d69-bbd2-9e390fbce465'	System	22 Aug 2020 00:44:59
User entered 'None (0)'	System	22 Aug 2020 00:44:59

FDA-CBER-2022-1614-0647436

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:44:43', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '7084d041-7ae7-4d69-bbd2-9e390fbce465'	System	22 Aug 2020 00:44:59
User entered 'None (0)'	System	22 Aug 2020 00:44:59

FDA-CBER-2022-1614-0647437

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:44:47', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '7084d041-7ae7-4d69-bbd2-9e390fbce465'	System	22 Aug 2020 00:44:59
User entered 'None (0)'	System	22 Aug 2020 00:44:59

FDA-CBER-2022-1614-0647438

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:44:49', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '7084d041-7ae7-4d69-bbd2-9e390fbce465'	System	22 Aug 2020 00:44:59
User entered 'None (0)'	System	22 Aug 2020 00:44:59

FDA-CBER-2022-1614-0647439

US3232048

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:44:55', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '7084d041-7ae7-4d69-bbd2-9e390fbce465'	System	22 Aug 2020 00:44:59
User entered 'No (N)'	System	22 Aug 2020 00:44:59

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-21T19:44:58', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '7084d041-7ae7-4d69-bbd2-9e390fbce465'	System	22 Aug 2020 00:44:59
User entered '21 Aug 2020 19:44'	System	22 Aug 2020 00:44:59

FDA-CBER-2022-1614-0647441

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Aug 2020 14:45'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647442

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647443

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 2'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647444

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:52:00', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b6c991a7-22af-47fc-90f3-a4d8d7b94af0'	System	23 Aug 2020 00:52:19
User entered 'None (0)'	System	23 Aug 2020 00:52:19

FDA-CBER-2022-1614-0647445

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:52:03', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b6c991a7-22af-47fc-90f3-a4d8d7b94af0'	System	23 Aug 2020 00:52:19
User entered 'None (0)'	System	23 Aug 2020 00:52:19

FDA-CBER-2022-1614-0647446

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:52:05', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b6c991a7-22af-47fc-90f3-a4d8d7b94af0'	System	23 Aug 2020 00:52:19
User entered 'None (0)'	System	23 Aug 2020 00:52:19

FDA-CBER-2022-1614-0647447

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:52:07', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b6c991a7-22af-47fc-90f3-a4d8d7b94af0'	System	23 Aug 2020 00:52:19
User entered 'None (0)'	System	23 Aug 2020 00:52:19

FDA-CBER-2022-1614-0647448

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:52:10', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b6c991a7-22af-47fc-90f3-a4d8d7b94af0'	System	23 Aug 2020 00:52:19
User entered 'None (0)'	System	23 Aug 2020 00:52:19

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:52:12', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b6c991a7-22af-47fc-90f3-a4d8d7b94af0'	System	23 Aug 2020 00:52:19
User entered 'None (0)'	System	23 Aug 2020 00:52:19

FDA-CBER-2022-1614-0647450

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:52:15', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b6c991a7-22af-47fc-90f3-a4d8d7b94af0'	System	23 Aug 2020 00:52:19
User entered 'No (N)'	System	23 Aug 2020 00:52:19

FDA-CBER-2022-1614-0647451

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-22T19:52:17', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b6c991a7-22af-47fc-90f3-a4d8d7b94af0'	System	23 Aug 2020 00:52:19
User entered '22 Aug 2020 19:52'	System	23 Aug 2020 00:52:19

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647453

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647454

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 3'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647455

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:36', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b59b0bc7-3cd6-476b-aafd-b29c0537caf8'	System	24 Aug 2020 00:46:57
User entered 'None (0)'	System	24 Aug 2020 00:46:57

FDA-CBER-2022-1614-0647456

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:40', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b59b0bc7-3cd6-476b-aafd-b29c0537caf8'	System	24 Aug 2020 00:46:57
User entered 'None (0)'	System	24 Aug 2020 00:46:57

FDA-CBER-2022-1614-0647457

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:42', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b59b0bc7-3cd6-476b-aafd-b29c0537caf8'	System	24 Aug 2020 00:46:57
User entered 'None (0)'	System	24 Aug 2020 00:46:57

FDA-CBER-2022-1614-0647458

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:44', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b59b0bc7-3cd6-476b-aafd-b29c0537caf8'	System	24 Aug 2020 00:46:57
User entered 'None (0)'	System	24 Aug 2020 00:46:57

FDA-CBER-2022-1614-0647459

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:46', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b59b0bc7-3cd6-476b-aafd-b29c0537caf8'	System	24 Aug 2020 00:46:57
User entered 'None (0)'	System	24 Aug 2020 00:46:57

FDA-CBER-2022-1614-0647460

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:49', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b59b0bc7-3cd6-476b-aafd-b29c0537caf8'	System	24 Aug 2020 00:46:57
User entered 'None (0)'	System	24 Aug 2020 00:46:57

FDA-CBER-2022-1614-0647461

US3232048

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:53', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b59b0bc7-3cd6-476b-aafd-b29c0537caf8'	System	24 Aug 2020 00:46:57
User entered 'No (N)'	System	24 Aug 2020 00:46:57

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-23T19:46:55', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'b59b0bc7-3cd6-476b-aafd-b29c0537caf8'	System	24 Aug 2020 00:46:57
User entered '23 Aug 2020 19:46'	System	24 Aug 2020 00:46:57

FDA-CBER-2022-1614-0647463

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647464

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647465

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 4'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647466

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:01:10', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd24b667e-e837-49b5-8f9b-9fd5d6e73e02'	System	25 Aug 2020 01:01:33
User entered 'None (0)'	System	25 Aug 2020 01:01:33

FDA-CBER-2022-1614-0647467

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:01:13', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd24b667e-e837-49b5-8f9b-9fd5d6e73e02'	System	25 Aug 2020 01:01:33
User entered 'None (0)'	System	25 Aug 2020 01:01:33

FDA-CBER-2022-1614-0647468

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:01:15', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd24b667e-e837-49b5-8f9b-9fd5d6e73e02'	System	25 Aug 2020 01:01:33
User entered 'None (0)'	System	25 Aug 2020 01:01:33

FDA-CBER-2022-1614-0647469

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:01:17', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd24b667e-e837-49b5-8f9b-9fd5d6e73e02'	System	25 Aug 2020 01:01:33
User entered 'None (0)'	System	25 Aug 2020 01:01:33

FDA-CBER-2022-1614-0647470

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:01:19', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd24b667e-e837-49b5-8f9b-9fd5d6e73e02'	System	25 Aug 2020 01:01:33
User entered 'None (0)'	System	25 Aug 2020 01:01:33

FDA-CBER-2022-1614-0647471

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:01:22', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd24b667e-e837-49b5-8f9b-9fd5d6e73e02'	System	25 Aug 2020 01:01:33
User entered 'None (0)'	System	25 Aug 2020 01:01:33

FDA-CBER-2022-1614-0647472

US3232048

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:01:26', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd24b667e-e837-49b5-8f9b-9fd5d6e73e02'	System	25 Aug 2020 01:01:33
User entered 'No (N)'	System	25 Aug 2020 01:01:33

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-24T20:01:29', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd24b667e-e837-49b5-8f9b-9fd5d6e73e02'	System	25 Aug 2020 01:01:33
User entered '24 Aug 2020 20:01'	System	25 Aug 2020 01:01:33

FDA-CBER-2022-1614-0647474

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647475

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647476

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 5'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647477

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:51', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'be231061-ad73-4a6f-9384-053c729639f3'	System	26 Aug 2020 01:15:15
User entered 'None (0)'	System	26 Aug 2020 01:15:15

FDA-CBER-2022-1614-0647478

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:54', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'be231061-ad73-4a6f-9384-053c729639f3'	System	26 Aug 2020 01:15:15
User entered 'None (0)'	System	26 Aug 2020 01:15:15

FDA-CBER-2022-1614-0647479

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:56', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'be231061-ad73-4a6f-9384-053c729639f3'	System	26 Aug 2020 01:15:15
User entered 'None (0)'	System	26 Aug 2020 01:15:15

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:14:58', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'be231061-ad73-4a6f-9384-053c729639f3'	System	26 Aug 2020 01:15:15
User entered 'None (0)'	System	26 Aug 2020 01:15:15

FDA-CBER-2022-1614-0647481

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:15:00', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'be231061-ad73-4a6f-9384-053c729639f3'	System	26 Aug 2020 01:15:15
User entered 'None (0)'	System	26 Aug 2020 01:15:15

FDA-CBER-2022-1614-0647482

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:15:03', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'be231061-ad73-4a6f-9384-053c729639f3'	System	26 Aug 2020 01:15:15
User entered 'None (0)'	System	26 Aug 2020 01:15:15

FDA-CBER-2022-1614-0647483

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:15:06', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'be231061-ad73-4a6f-9384-053c729639f3'	System	26 Aug 2020 01:15:15
User entered 'No (N)'	System	26 Aug 2020 01:15:15

FDA-CBER-2022-1614-0647484

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-25T20:15:09', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'be231061-ad73-4a6f-9384-053c729639f3'	System	26 Aug 2020 01:15:15
User entered '25 Aug 2020 20:15'	System	26 Aug 2020 01:15:15

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647486

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647487

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 6'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647488

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:13:13', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '30eb687a-d57c-4c53-8220-aaeb998188d6'	System	27 Aug 2020 01:13:36
User entered 'None (0)'	System	27 Aug 2020 01:13:36

FDA-CBER-2022-1614-0647489

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:13:16', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '30eb687a-d57c-4c53-8220-aaeb998188d6'	System	27 Aug 2020 01:13:36
User entered 'None (0)'	System	27 Aug 2020 01:13:36

FDA-CBER-2022-1614-0647490

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:13:19', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '30eb687a-d57c-4c53-8220-aaeb998188d6'	System	27 Aug 2020 01:13:36
User entered 'None (0)'	System	27 Aug 2020 01:13:36

FDA-CBER-2022-1614-0647491

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:13:21', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '30eb687a-d57c-4c53-8220-aaeb998188d6'	System	27 Aug 2020 01:13:36
User entered 'None (0)'	System	27 Aug 2020 01:13:36

FDA-CBER-2022-1614-0647492

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:13:23', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '30eb687a-d57c-4c53-8220-aaeb998188d6'	System	27 Aug 2020 01:13:36
User entered 'None (0)'	System	27 Aug 2020 01:13:36

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:13:25', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '30eb687a-d57c-4c53-8220-aaeb998188d6'	System	27 Aug 2020 01:13:36
User entered 'None (0)'	System	27 Aug 2020 01:13:36

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:13:31', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '30eb687a-d57c-4c53-8220-aaeb998188d6'	System	27 Aug 2020 01:13:36
User entered 'No (N)'	System	27 Aug 2020 01:13:36

FDA-CBER-2022-1614-0647495

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-26T20:13:34', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '30eb687a-d57c-4c53-8220-aaeb998188d6'	System	27 Aug 2020 01:13:36
User entered '26 Aug 2020 20:13'	System	27 Aug 2020 01:13:36

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647497

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647498

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 7'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647499

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:26', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '07779d99-ed11-4fad-a1e0-51e8b76db578'	System	28 Aug 2020 01:23:51
User entered 'None (0)'	System	28 Aug 2020 01:23:51

FDA-CBER-2022-1614-0647500

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:28', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '07779d99-ed11-4fad-a1e0-51e8b76db578'	System	28 Aug 2020 01:23:51
User entered 'None (0)'	System	28 Aug 2020 01:23:51

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:30', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '07779d99-ed11-4fad-a1e0-51e8b76db578'	System	28 Aug 2020 01:23:51
User entered 'None (0)'	System	28 Aug 2020 01:23:51

FDA-CBER-2022-1614-0647502

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:33', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '07779d99-ed11-4fad-a1e0-51e8b76db578'	System	28 Aug 2020 01:23:51
User entered 'None (0)'	System	28 Aug 2020 01:23:51

FDA-CBER-2022-1614-0647503

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:35', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '07779d99-ed11-4fad-a1e0-51e8b76db578'	System	28 Aug 2020 01:23:51
User entered 'None (0)'	System	28 Aug 2020 01:23:51

FDA-CBER-2022-1614-0647504

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:38', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '07779d99-ed11-4fad-a1e0-51e8b76db578'	System	28 Aug 2020 01:23:51
User entered 'None (0)'	System	28 Aug 2020 01:23:51

US3232048

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:45', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '07779d99-ed11-4fad-a1e0-51e8b76db578'	System	28 Aug 2020 01:23:51
User entered 'Yes (Y)'	System	28 Aug 2020 01:23:51

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-08-27T20:23:47', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '07779d99-ed11-4fad-a1e0-51e8b76db578'	System	28 Aug 2020 01:23:51
User entered '27 Aug 2020 20:23'	System	28 Aug 2020 01:23:51

FDA-CBER-2022-1614-0647507

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647508

US3232048
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647509

US3232048
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:35:49
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:56:33

FDA-CBER-2022-1614-0647510

US3232048
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:35:49
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '28 Aug 2020'	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:56:33

US3232048
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:35:49
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:56:33

US3232048
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:35:49
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:56:33

FDA-CBER-2022-1614-0647513

US3232048
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:35:49
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 21:56:39

US3232048
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:35:49
User entered '1'	(b) (4), (b) (6) System	28 Aug 2020 21:56:39

FDA-CBER-2022-1614-0647515

US3232048
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:35:49
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	04 Sep 2020 15:04:32

FDA-CBER-2022-1614-0647516

US3232048
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:35:49
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '4 Sep 2020'	Jerrica Sullivan (b) (4) (b) (4)	04 Sep 2020 15:04:32

FDA-CBER-2022-1614-0647517

US3232048
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:35:49
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4) (b) (4)	04 Sep 2020 15:04:32

FDA-CBER-2022-1614-0647518

US3232048
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:35:49
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	04 Sep 2020 15:04:32

FDA-CBER-2022-1614-0647519

US3232048
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 09:35:49
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	04 Sep 2020 15:04:36

FDA-CBER-2022-1614-0647520

US3232048
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:35:49
User entered '1'	(b) (4), (b) (6) System	04 Sep 2020 15:04:36

FDA-CBER-2022-1614-0647521

US3232048
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:30:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 15:08:09

FDA-CBER-2022-1614-0647522

US3232048
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:30:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Sep 2020'	Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 15:08:09

FDA-CBER-2022-1614-0647523

US3232048
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:30:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 15:08:09

US3232048
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:30:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 15:08:09

FDA-CBER-2022-1614-0647525

US3232048
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:30:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 15:07:57

FDA-CBER-2022-1614-0647526

US3232048
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:30:46
User entered '1'	(b) (4), (b) (6) System	12 Sep 2020 15:07:57

FDA-CBER-2022-1614-0647527

US3232048
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:48:19

FDA-CBER-2022-1614-0647528

US3232048
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '18 Sep 2020'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:48:19

FDA-CBER-2022-1614-0647529

US3232048
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:48:19

US3232048
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'VISIT2'	System	18 Sep 2020 17:48:19

FDA-CBER-2022-1614-0647531

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User accepted default value 'Pre-Dose (PREDOSE)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647532

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647533

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '18 Sep 2020'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647534

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '09:40'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647535

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '18 Sep 2020 09:40'	System	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647536

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '98.3' F	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647537

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (Oral)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647538

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647539

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '78'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647540

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'bpm'	System	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647541

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '17'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647542

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'breaths/min'	System	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647543

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '106'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647544

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'mmHg'	System	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647545

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '60'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647546

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'mmHg'	System	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647547

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User accepted default value 'Post-Dose (POSTDOSE)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647548

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647549

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '18 Sep 2020'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647550

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12:04'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647551

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '18 Sep 2020 12:04'	System	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647552

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '97.3' F	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647553

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Other (Other)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647554

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'temporal'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647555

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '83'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647556

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'bpm'	System	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647557

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '18'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647558

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'breaths/min'	System	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647559

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '112'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647560

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'mmHg'	System	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647561

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '60'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647562

US3232048
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'mmHg'	System	18 Sep 2020 17:51:02

FDA-CBER-2022-1614-0647563

US3232048
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:04:06
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:09

FDA-CBER-2022-1614-0647564

US3232048
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:04:06
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '18 Sep 2020'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:09

US3232048
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647566

US3232048
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647567

US3232048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 16:46:08

US3232048
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647569

US3232048
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '18 Sep 2020'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 16:46:08

US3232048
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '11:42'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647571

US3232048
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '18 Sep 2020 11:42'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647572

US3232048
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Right Arm (RIGHT ARM)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647573

US3232048
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'ONCE'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647574

US3232048
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:04:06
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647575

US3232048
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:35

FDA-CBER-2022-1614-0647576

US3232048
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 18SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 18:29:42
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 18SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'confirmed that the samples were taken and will be shipped.' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 19:05:58
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 18SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Oct 2020 17:55:52
User entered '18 Sep 2020'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:35

FDA-CBER-2022-1614-0647577

US3232048
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '10:00'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:35

FDA-CBER-2022-1614-0647578

US3232048
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '18 Sep 2020 10:00'	System	18 Sep 2020 17:51:35

FDA-CBER-2022-1614-0647579

US3232048
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 16:04:06
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '18 Sep 2020'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:46

FDA-CBER-2022-1614-0647580

US3232048
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:04:06
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:46

FDA-CBER-2022-1614-0647581

US3232048
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:04:06
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:46

FDA-CBER-2022-1614-0647582

US3232048
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:04:06
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '09:55'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:46

FDA-CBER-2022-1614-0647583

US3232048
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:04:06
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '18 Sep 2020 09:55'	System	18 Sep 2020 17:51:46

FDA-CBER-2022-1614-0647584

US3232048
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:04:06
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:46

FDA-CBER-2022-1614-0647585

US3232048
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:04:06
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:46

FDA-CBER-2022-1614-0647586

US3232048
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:04:06
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:46

FDA-CBER-2022-1614-0647587

US3232048
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:04:06
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered empty.	System	18 Sep 2020 17:51:46

FDA-CBER-2022-1614-0647588

US3232048
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 17:51:50

FDA-CBER-2022-1614-0647589

US3232048
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '1'	System	18 Sep 2020 17:51:50

FDA-CBER-2022-1614-0647590

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647591

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:02:32', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '99630de6-0c80-444b-8f67-0370dc9b2c71'	System	18 Sep 2020 17:03:12
User entered 'Yes (Y)'	System	18 Sep 2020 17:03:12

FDA-CBER-2022-1614-0647592

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:02:37', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '99630de6-0c80-444b-8f67-0370dc9b2c71'	System	18 Sep 2020 17:03:12
User entered '97.3'	System	18 Sep 2020 17:03:12

FDA-CBER-2022-1614-0647593

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:02:41', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '99630de6-0c80-444b-8f67-0370dc9b2c71'	System	18 Sep 2020 17:03:12
User entered 'No (N)'	System	18 Sep 2020 17:03:12

FDA-CBER-2022-1614-0647594

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:02:45', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '99630de6-0c80-444b-8f67-0370dc9b2c71'	System	18 Sep 2020 17:03:12
User entered '18 Sep 2020 12:02'	System	18 Sep 2020 17:03:12

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '18 Sep 2020 12:02'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647596

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '18 Sep 2020 14:32'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647597

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647598

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:46:19', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'fa78de19-6bd2-4443-bf2d-bdb6cff2d967'	System	18 Sep 2020 23:46:45
User entered 'Yes (Y)'	System	18 Sep 2020 23:46:45

FDA-CBER-2022-1614-0647599

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:46:27', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'fa78de19-6bd2-4443-bf2d-bdb6cff2d967'	System	18 Sep 2020 23:46:45
User entered '97.5'	System	18 Sep 2020 23:46:45

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:46:32', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'fa78de19-6bd2-4443-bf2d-bdb6cff2d967'	System	18 Sep 2020 23:46:45
User entered 'No (N)'	System	18 Sep 2020 23:46:45

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:46:43', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'fa78de19-6bd2-4443-bf2d-bdb6cff2d967'	System	18 Sep 2020 23:46:45
User entered '18 Sep 2020 18:46'	System	18 Sep 2020 23:46:45

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '18 Sep 2020 15:27'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647603

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647604

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 2'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647605

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T19:59:46', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '527e4dbc-3725-4271-bc87-4ae77d25cc3e'	System	20 Sep 2020 01:00:05
User entered 'Yes (Y)'	System	20 Sep 2020 01:00:05

FDA-CBER-2022-1614-0647606

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T19:59:52', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '527e4dbc-3725-4271-bc87-4ae77d25cc3e'	System	20 Sep 2020 01:00:05
User entered '97.7'	System	20 Sep 2020 01:00:05

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T19:59:57', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '527e4dbc-3725-4271-bc87-4ae77d25cc3e'	System	20 Sep 2020 01:00:05
User entered 'No (N)'	System	20 Sep 2020 01:00:05

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:03', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '527e4dbc-3725-4271-bc87-4ae77d25cc3e'	System	20 Sep 2020 01:00:05
User entered '19 Sep 2020 20:00'	System	20 Sep 2020 01:00:05

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647610

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647611

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 3'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647612

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:05', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '88d84631-4e40-45d1-a756-aef690c7a41b'	System	20 Sep 2020 23:16:25
User entered 'Yes (Y)'	System	20 Sep 2020 23:16:25

FDA-CBER-2022-1614-0647613

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:12', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '88d84631-4e40-45d1-a756-aef690c7a41b'	System	20 Sep 2020 23:16:25
User entered '97.8'	System	20 Sep 2020 23:16:25

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:16', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '88d84631-4e40-45d1-a756-aef690c7a41b'	System	20 Sep 2020 23:16:25
User entered 'No (N)'	System	20 Sep 2020 23:16:25

FDA-CBER-2022-1614-0647615

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:21', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '88d84631-4e40-45d1-a756-aef690c7a41b'	System	20 Sep 2020 23:16:25
User entered '20 Sep 2020 18:16'	System	20 Sep 2020 23:16:25

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647617

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647618

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 4'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647619

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T19:59:54', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'bd30c894-4756-42a7-979b-4cc67de983a5'	System	22 Sep 2020 01:00:46
User entered 'Yes (Y)'	System	22 Sep 2020 01:00:46

FDA-CBER-2022-1614-0647620

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T19:59:59', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'bd30c894-4756-42a7-979b-4cc67de983a5'	System	22 Sep 2020 01:00:46
User entered '98.0'	System	22 Sep 2020 01:00:46

FDA-CBER-2022-1614-0647621

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:00:37', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'bd30c894-4756-42a7-979b-4cc67de983a5'	System	22 Sep 2020 01:00:46
User entered 'No (N)'	System	22 Sep 2020 01:00:46

FDA-CBER-2022-1614-0647622

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:00:43', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'bd30c894-4756-42a7-979b-4cc67de983a5'	System	22 Sep 2020 01:00:46
User entered '21 Sep 2020 20:00'	System	22 Sep 2020 01:00:46

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647624

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647625

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 5'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647626

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:38:33', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4a949aa4-43a1-4e18-83d5-074450b658dc'	System	23 Sep 2020 01:38:50
User entered 'Yes (Y)'	System	23 Sep 2020 01:38:50

FDA-CBER-2022-1614-0647627

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:38:40', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4a949aa4-43a1-4e18-83d5-074450b658dc'	System	23 Sep 2020 01:38:50
User entered '97.7'	System	23 Sep 2020 01:38:50

FDA-CBER-2022-1614-0647628

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:38:44', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4a949aa4-43a1-4e18-83d5-074450b658dc'	System	23 Sep 2020 01:38:50
User entered 'No (N)'	System	23 Sep 2020 01:38:50

FDA-CBER-2022-1614-0647629

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:38:47', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '4a949aa4-43a1-4e18-83d5-074450b658dc'	System	23 Sep 2020 01:38:50
User entered '22 Sep 2020 20:38'	System	23 Sep 2020 01:38:50

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647631

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647632

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 6'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647633

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:26:55', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '1f8a6ae2-9f27-4876-b91f-8c4d554eb837'	System	24 Sep 2020 03:27:17
User entered 'Yes (Y)'	System	24 Sep 2020 03:27:17

FDA-CBER-2022-1614-0647634

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:02', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '1f8a6ae2-9f27-4876-b91f-8c4d554eb837'	System	24 Sep 2020 03:27:17
User entered '97.7'	System	24 Sep 2020 03:27:17

FDA-CBER-2022-1614-0647635

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:08', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '1f8a6ae2-9f27-4876-b91f-8c4d554eb837'	System	24 Sep 2020 03:27:17
User entered 'No (N)'	System	24 Sep 2020 03:27:17

FDA-CBER-2022-1614-0647636

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:13', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '1f8a6ae2-9f27-4876-b91f-8c4d554eb837'	System	24 Sep 2020 03:27:17
User entered '23 Sep 2020 22:27'	System	24 Sep 2020 03:27:17

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647638

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647639

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 7'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647640

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:09:29', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd659ac03-1159-4a27-9be7-863f24126fe9'	System	25 Sep 2020 00:09:45
User entered 'Yes (Y)'	System	25 Sep 2020 00:09:45

FDA-CBER-2022-1614-0647641

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:09:34', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd659ac03-1159-4a27-9be7-863f24126fe9'	System	25 Sep 2020 00:09:45
User entered '98.0'	System	25 Sep 2020 00:09:45

FDA-CBER-2022-1614-0647642

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:09:37', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd659ac03-1159-4a27-9be7-863f24126fe9'	System	25 Sep 2020 00:09:45
User entered 'No (N)'	System	25 Sep 2020 00:09:45

FDA-CBER-2022-1614-0647643

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:09:40', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd659ac03-1159-4a27-9be7-863f24126fe9'	System	25 Sep 2020 00:09:45
User entered '24 Sep 2020 19:09'	System	25 Sep 2020 00:09:45

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647645

US3232048
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647646

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647647

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:02:50', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'add34dbe-560d-463f-803b-dafd25149f4f'	System	18 Sep 2020 17:03:27
User entered 'None (1)'	System	18 Sep 2020 17:03:27

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:02:58', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'add34dbe-560d-463f-803b-dafd25149f4f'	System	18 Sep 2020 17:03:27
User entered 'No (N)'	System	18 Sep 2020 17:03:27

FDA-CBER-2022-1614-0647649

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:03:01', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'add34dbe-560d-463f-803b-dafd25149f4f'	System	18 Sep 2020 17:03:27
User entered 'No (N)'	System	18 Sep 2020 17:03:27

FDA-CBER-2022-1614-0647650

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:03:06', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'add34dbe-560d-463f-803b-dafd25149f4f'	System	18 Sep 2020 17:03:27
User entered 'None (1)'	System	18 Sep 2020 17:03:27

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:03:09', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'add34dbe-560d-463f-803b-dafd25149f4f'	System	18 Sep 2020 17:03:27
User entered '18 Sep 2020 12:03'	System	18 Sep 2020 17:03:27

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '18 Sep 2020 12:02'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647653

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '18 Sep 2020 14:32'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647654

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647655

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:46:59', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '851db0d8-73aa-4591-a6d9-99cd4dc8b3ce'	System	18 Sep 2020 23:47:17
User entered 'None (1)'	System	18 Sep 2020 23:47:17

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:03', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '851db0d8-73aa-4591-a6d9-99cd4dc8b3ce'	System	18 Sep 2020 23:47:17
User entered 'No (N)'	System	18 Sep 2020 23:47:17

FDA-CBER-2022-1614-0647657

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:07', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '851db0d8-73aa-4591-a6d9-99cd4dc8b3ce'	System	18 Sep 2020 23:47:17
User entered 'No (N)'	System	18 Sep 2020 23:47:17

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:09', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '851db0d8-73aa-4591-a6d9-99cd4dc8b3ce'	System	18 Sep 2020 23:47:17
User entered 'None (1)'	System	18 Sep 2020 23:47:17

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:13', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '851db0d8-73aa-4591-a6d9-99cd4dc8b3ce'	System	18 Sep 2020 23:47:17
User entered '18 Sep 2020 18:47'	System	18 Sep 2020 23:47:17

FDA-CBER-2022-1614-0647660

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '18 Sep 2020 15:27'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647661

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647662

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 2'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647663

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:15', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e55521b8-81e3-4ac8-ac1b-6388bd7e2c67'	System	20 Sep 2020 01:00:36
User entered 'None (1)'	System	20 Sep 2020 01:00:36

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:19', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e55521b8-81e3-4ac8-ac1b-6388bd7e2c67'	System	20 Sep 2020 01:00:36
User entered 'No (N)'	System	20 Sep 2020 01:00:36

FDA-CBER-2022-1614-0647665

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:22', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e55521b8-81e3-4ac8-ac1b-6388bd7e2c67'	System	20 Sep 2020 01:00:36
User entered 'No (N)'	System	20 Sep 2020 01:00:36

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:28', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e55521b8-81e3-4ac8-ac1b-6388bd7e2c67'	System	20 Sep 2020 01:00:36
User entered 'None (1)'	System	20 Sep 2020 01:00:36

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:33', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e55521b8-81e3-4ac8-ac1b-6388bd7e2c67'	System	20 Sep 2020 01:00:36
User entered '19 Sep 2020 20:00'	System	20 Sep 2020 01:00:36

FDA-CBER-2022-1614-0647668

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647669

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647670

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 3'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647671

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:26', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c5656822-1df1-43e7-ab18-c0dca613b2c1'	System	20 Sep 2020 23:16:42
User entered 'None (1)'	System	20 Sep 2020 23:16:42

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:30', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c5656822-1df1-43e7-ab18-c0dca613b2c1'	System	20 Sep 2020 23:16:42
User entered 'No (N)'	System	20 Sep 2020 23:16:42

FDA-CBER-2022-1614-0647673

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:34', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c5656822-1df1-43e7-ab18-c0dca613b2c1'	System	20 Sep 2020 23:16:42
User entered 'No (N)'	System	20 Sep 2020 23:16:42

FDA-CBER-2022-1614-0647674

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:37', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c5656822-1df1-43e7-ab18-c0dca613b2c1'	System	20 Sep 2020 23:16:42
User entered 'None (1)'	System	20 Sep 2020 23:16:42

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:40', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c5656822-1df1-43e7-ab18-c0dca613b2c1'	System	20 Sep 2020 23:16:42
User entered '20 Sep 2020 18:16'	System	20 Sep 2020 23:16:42

FDA-CBER-2022-1614-0647676

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647677

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647678

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 4'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647679

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:00:48', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '77279f12-7d31-4417-85d2-392236cdf401'	System	22 Sep 2020 01:01:25
User entered 'None (1)'	System	22 Sep 2020 01:01:25

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:00:56', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '77279f12-7d31-4417-85d2-392236cdf401'	System	22 Sep 2020 01:01:25
User entered 'No (N)'	System	22 Sep 2020 01:01:25

FDA-CBER-2022-1614-0647681

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:01:11', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '77279f12-7d31-4417-85d2-392236cdf401'	System	22 Sep 2020 01:01:25
User entered 'No (N)'	System	22 Sep 2020 01:01:25

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:01:15', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '77279f12-7d31-4417-85d2-392236cdf401'	System	22 Sep 2020 01:01:25
User entered 'None (1)'	System	22 Sep 2020 01:01:25

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:01:18', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '77279f12-7d31-4417-85d2-392236cdf401'	System	22 Sep 2020 01:01:25
User entered '21 Sep 2020 20:01'	System	22 Sep 2020 01:01:25

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647685

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647686

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 5'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647687

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:38:52', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '510cd098-a9c1-4496-b955-22be82f05ea1'	System	23 Sep 2020 01:39:07
User entered 'None (1)'	System	23 Sep 2020 01:39:07

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:38:55', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '510cd098-a9c1-4496-b955-22be82f05ea1'	System	23 Sep 2020 01:39:07
User entered 'No (N)'	System	23 Sep 2020 01:39:07

FDA-CBER-2022-1614-0647689

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:38:58', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '510cd098-a9c1-4496-b955-22be82f05ea1'	System	23 Sep 2020 01:39:07
User entered 'No (N)'	System	23 Sep 2020 01:39:07

FDA-CBER-2022-1614-0647690

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:39:01', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '510cd098-a9c1-4496-b955-22be82f05ea1'	System	23 Sep 2020 01:39:07
User entered 'None (1)'	System	23 Sep 2020 01:39:07

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:39:04', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '510cd098-a9c1-4496-b955-22be82f05ea1'	System	23 Sep 2020 01:39:07
User entered '22 Sep 2020 20:39'	System	23 Sep 2020 01:39:07

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647693

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647694

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 6'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647695

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:18', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'aa5b7d2f-1b64-4f5a-b4cf-a42fd969c465'	System	24 Sep 2020 03:27:39
User entered 'None (1)'	System	24 Sep 2020 03:27:39

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:24', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'aa5b7d2f-1b64-4f5a-b4cf-a42fd969c465'	System	24 Sep 2020 03:27:39
User entered 'No (N)'	System	24 Sep 2020 03:27:39

FDA-CBER-2022-1614-0647697

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:28', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'aa5b7d2f-1b64-4f5a-b4cf-a42fd969c465'	System	24 Sep 2020 03:27:39
User entered 'No (N)'	System	24 Sep 2020 03:27:39

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:32', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'aa5b7d2f-1b64-4f5a-b4cf-a42fd969c465'	System	24 Sep 2020 03:27:39
User entered 'None (1)'	System	24 Sep 2020 03:27:39

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:36', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'aa5b7d2f-1b64-4f5a-b4cf-a42fd969c465'	System	24 Sep 2020 03:27:39
User entered '23 Sep 2020 22:27'	System	24 Sep 2020 03:27:39

FDA-CBER-2022-1614-0647700

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647701

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647702

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 7'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647703

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:09:43', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '59e74862-6342-4dc4-8385-faada590acc2'	System	25 Sep 2020 00:09:58
User entered 'None (1)'	System	25 Sep 2020 00:09:58

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:09:47', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '59e74862-6342-4dc4-8385-faada590acc2'	System	25 Sep 2020 00:09:58
User entered 'No (N)'	System	25 Sep 2020 00:09:58

FDA-CBER-2022-1614-0647705

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:09:49', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '59e74862-6342-4dc4-8385-faada590acc2'	System	25 Sep 2020 00:09:58
User entered 'No (N)'	System	25 Sep 2020 00:09:58

FDA-CBER-2022-1614-0647706

US3232048

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:09:51', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '59e74862-6342-4dc4-8385-faada590acc2'	System	25 Sep 2020 00:09:58
User entered 'None (1)'	System	25 Sep 2020 00:09:58

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:09:54', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '59e74862-6342-4dc4-8385-faada590acc2'	System	25 Sep 2020 00:09:58
User entered '24 Sep 2020 19:09'	System	25 Sep 2020 00:09:58

FDA-CBER-2022-1614-0647708

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647709

US3232048
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647710

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647711

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:03:13', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3dddd284-3e77-477e-bb97-53a24b5b8e24'	System	18 Sep 2020 17:03:50
User entered 'None (0)'	System	18 Sep 2020 17:03:50

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:03:16', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3dddd284-3e77-477e-bb97-53a24b5b8e24'	System	18 Sep 2020 17:03:50
User entered 'None (0)'	System	18 Sep 2020 17:03:50

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:03:18', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3dddd284-3e77-477e-bb97-53a24b5b8e24'	System	18 Sep 2020 17:03:50
User entered 'None (0)'	System	18 Sep 2020 17:03:50

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:03:20', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3dddd284-3e77-477e-bb97-53a24b5b8e24'	System	18 Sep 2020 17:03:50
User entered 'None (0)'	System	18 Sep 2020 17:03:50

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:03:23', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3dddd284-3e77-477e-bb97-53a24b5b8e24'	System	18 Sep 2020 17:03:50
User entered 'None (0)'	System	18 Sep 2020 17:03:50

FDA-CBER-2022-1614-0647716

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:03:25', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3dddd284-3e77-477e-bb97-53a24b5b8e24'	System	18 Sep 2020 17:03:50
User entered 'None (0)'	System	18 Sep 2020 17:03:50

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:03:28', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3dddd284-3e77-477e-bb97-53a24b5b8e24'	System	18 Sep 2020 17:03:50
User entered 'No (N)'	System	18 Sep 2020 17:03:50

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T12:03:31', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '3dddd284-3e77-477e-bb97-53a24b5b8e24'	System	18 Sep 2020 17:03:50
User entered '18 Sep 2020 12:03'	System	18 Sep 2020 17:03:50

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '18 Sep 2020 12:02'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647720

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '18 Sep 2020 14:32'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647721

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647722

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:19', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd07f3e82-aaca-4555-9bbf-01cd1fb3b89a'	System	18 Sep 2020 23:47:49
User entered 'None (0)'	System	18 Sep 2020 23:47:49

FDA-CBER-2022-1614-0647723

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:22', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd07f3e82-aaca-4555-9bbf-01cd1fb3b89a'	System	18 Sep 2020 23:47:49
User entered 'None (0)'	System	18 Sep 2020 23:47:49

FDA-CBER-2022-1614-0647724

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:25', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd07f3e82-aaca-4555-9bbf-01cd1fb3b89a'	System	18 Sep 2020 23:47:49
User entered 'None (0)'	System	18 Sep 2020 23:47:49

FDA-CBER-2022-1614-0647725

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:28', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd07f3e82-aaca-4555-9bbf-01cd1fb3b89a'	System	18 Sep 2020 23:47:49
User entered 'None (0)'	System	18 Sep 2020 23:47:49

FDA-CBER-2022-1614-0647726

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:31', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd07f3e82-aaca-4555-9bbf-01cd1fb3b89a'	System	18 Sep 2020 23:47:49
User entered 'None (0)'	System	18 Sep 2020 23:47:49

FDA-CBER-2022-1614-0647727

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:34', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd07f3e82-aaca-4555-9bbf-01cd1fb3b89a'	System	18 Sep 2020 23:47:49
User entered 'None (0)'	System	18 Sep 2020 23:47:49

FDA-CBER-2022-1614-0647728

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:37', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd07f3e82-aaca-4555-9bbf-01cd1fb3b89a'	System	18 Sep 2020 23:47:49
User entered 'No (N)'	System	18 Sep 2020 23:47:49

FDA-CBER-2022-1614-0647729

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-18T18:47:46', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'd07f3e82-aaca-4555-9bbf-01cd1fb3b89a'	System	18 Sep 2020 23:47:49
User entered '18 Sep 2020 18:47'	System	18 Sep 2020 23:47:49

FDA-CBER-2022-1614-0647730

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '18 Sep 2020 15:27'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647731

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647732

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 2'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647733

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:38', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e8affd06-4d39-455f-91ec-7b8ffe7acdfd'	System	20 Sep 2020 01:01:17
User entered 'None (0)'	System	20 Sep 2020 01:01:17

FDA-CBER-2022-1614-0647734

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:41', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e8affd06-4d39-455f-91ec-7b8ffe7acdfd'	System	20 Sep 2020 01:01:17
User entered 'None (0)'	System	20 Sep 2020 01:01:17

FDA-CBER-2022-1614-0647735

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:43', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e8affd06-4d39-455f-91ec-7b8ffe7acdfd'	System	20 Sep 2020 01:01:17
User entered 'None (0)'	System	20 Sep 2020 01:01:17

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:45', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e8affd06-4d39-455f-91ec-7b8ffe7acdfd'	System	20 Sep 2020 01:01:17
User entered 'None (0)'	System	20 Sep 2020 01:01:17

FDA-CBER-2022-1614-0647737

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:51', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e8affd06-4d39-455f-91ec-7b8ffe7acdfd'	System	20 Sep 2020 01:01:17
User entered 'None (0)'	System	20 Sep 2020 01:01:17

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:54', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e8affd06-4d39-455f-91ec-7b8ffe7acdfd'	System	20 Sep 2020 01:01:17
User entered 'None (0)'	System	20 Sep 2020 01:01:17

FDA-CBER-2022-1614-0647739

US3232048

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:00:58', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e8affd06-4d39-455f-91ec-7b8ffe7acdfd'	System	20 Sep 2020 01:01:17
User entered 'No (N)'	System	20 Sep 2020 01:01:17

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-19T20:01:12', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'e8affd06-4d39-455f-91ec-7b8ffe7acdfd'	System	20 Sep 2020 01:01:17
User entered '19 Sep 2020 20:01'	System	20 Sep 2020 01:01:17

FDA-CBER-2022-1614-0647741

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647742

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647743

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 3'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647744

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:46', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'adc331db-c08a-4230-be2c-045db645474f'	System	20 Sep 2020 23:18:52
User entered 'None (0)'	System	20 Sep 2020 23:18:52

FDA-CBER-2022-1614-0647745

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:50', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'adc331db-c08a-4230-be2c-045db645474f'	System	20 Sep 2020 23:18:52
User entered 'None (0)'	System	20 Sep 2020 23:18:52

FDA-CBER-2022-1614-0647746

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:53', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'adc331db-c08a-4230-be2c-045db645474f'	System	20 Sep 2020 23:18:52
User entered 'None (0)'	System	20 Sep 2020 23:18:52

FDA-CBER-2022-1614-0647747

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:56', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'adc331db-c08a-4230-be2c-045db645474f'	System	20 Sep 2020 23:18:52
User entered 'None (0)'	System	20 Sep 2020 23:18:52

FDA-CBER-2022-1614-0647748

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:16:59', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'adc331db-c08a-4230-be2c-045db645474f'	System	20 Sep 2020 23:18:52
User entered 'None (0)'	System	20 Sep 2020 23:18:52

FDA-CBER-2022-1614-0647749

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:17:06', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'adc331db-c08a-4230-be2c-045db645474f'	System	20 Sep 2020 23:18:52
User entered 'None (0)'	System	20 Sep 2020 23:18:52

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:17:19', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'adc331db-c08a-4230-be2c-045db645474f'	System	20 Sep 2020 23:18:52
User entered 'No (N)'	System	20 Sep 2020 23:18:52

FDA-CBER-2022-1614-0647751

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-20T18:18:49', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'adc331db-c08a-4230-be2c-045db645474f'	System	20 Sep 2020 23:18:52
User entered '20 Sep 2020 18:18'	System	20 Sep 2020 23:18:52

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647753

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647754

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 4'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647755

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:01:24', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '5bc2629c-2b37-4076-99c6-f88f93a3a697'	System	22 Sep 2020 01:01:54
User entered 'None (0)'	System	22 Sep 2020 01:01:54

FDA-CBER-2022-1614-0647756

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:01:26', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '5bc2629c-2b37-4076-99c6-f88f93a3a697'	System	22 Sep 2020 01:01:54
User entered 'None (0)'	System	22 Sep 2020 01:01:54

FDA-CBER-2022-1614-0647757

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:01:30', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '5bc2629c-2b37-4076-99c6-f88f93a3a697'	System	22 Sep 2020 01:01:54
User entered 'None (0)'	System	22 Sep 2020 01:01:54

FDA-CBER-2022-1614-0647758

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:01:38', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '5bc2629c-2b37-4076-99c6-f88f93a3a697'	System	22 Sep 2020 01:01:54
User entered 'None (0)'	System	22 Sep 2020 01:01:54

FDA-CBER-2022-1614-0647759

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:01:41', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '5bc2629c-2b37-4076-99c6-f88f93a3a697'	System	22 Sep 2020 01:01:54
User entered 'None (0)'	System	22 Sep 2020 01:01:54

FDA-CBER-2022-1614-0647760

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:01:45', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '5bc2629c-2b37-4076-99c6-f88f93a3a697'	System	22 Sep 2020 01:01:54
User entered 'None (0)'	System	22 Sep 2020 01:01:54

FDA-CBER-2022-1614-0647761

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:01:48', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '5bc2629c-2b37-4076-99c6-f88f93a3a697'	System	22 Sep 2020 01:01:54
User entered 'No (N)'	System	22 Sep 2020 01:01:54

FDA-CBER-2022-1614-0647762

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-21T20:01:52', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '5bc2629c-2b37-4076-99c6-f88f93a3a697'	System	22 Sep 2020 01:01:54
User entered '21 Sep 2020 20:01'	System	22 Sep 2020 01:01:54

FDA-CBER-2022-1614-0647763

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647764

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647765

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 5'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647766

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:39:08', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ac65b458-9097-4fdc-b884-e7e499471f79'	System	23 Sep 2020 01:39:37
User entered 'None (0)'	System	23 Sep 2020 01:39:37

FDA-CBER-2022-1614-0647767

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:39:11', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ac65b458-9097-4fdc-b884-e7e499471f79'	System	23 Sep 2020 01:39:37
User entered 'None (0)'	System	23 Sep 2020 01:39:37

FDA-CBER-2022-1614-0647768

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:39:14', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ac65b458-9097-4fdc-b884-e7e499471f79'	System	23 Sep 2020 01:39:37
User entered 'None (0)'	System	23 Sep 2020 01:39:37

FDA-CBER-2022-1614-0647769

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:39:17', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ac65b458-9097-4fdc-b884-e7e499471f79'	System	23 Sep 2020 01:39:37
User entered 'None (0)'	System	23 Sep 2020 01:39:37

FDA-CBER-2022-1614-0647770

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:39:20', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ac65b458-9097-4fdc-b884-e7e499471f79'	System	23 Sep 2020 01:39:37
User entered 'None (0)'	System	23 Sep 2020 01:39:37

FDA-CBER-2022-1614-0647771

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:39:22', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ac65b458-9097-4fdc-b884-e7e499471f79'	System	23 Sep 2020 01:39:37
User entered 'None (0)'	System	23 Sep 2020 01:39:37

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:39:30', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ac65b458-9097-4fdc-b884-e7e499471f79'	System	23 Sep 2020 01:39:37
User entered 'No (N)'	System	23 Sep 2020 01:39:37

FDA-CBER-2022-1614-0647773

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-22T20:39:32', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ac65b458-9097-4fdc-b884-e7e499471f79'	System	23 Sep 2020 01:39:37
User entered '22 Sep 2020 20:39'	System	23 Sep 2020 01:39:37

FDA-CBER-2022-1614-0647774

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647775

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647776

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 6'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647777

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:40', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ea7a5103-8446-473a-a3bc-a70025ad070b'	System	24 Sep 2020 03:28:03
User entered 'None (0)'	System	24 Sep 2020 03:28:03

FDA-CBER-2022-1614-0647778

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:43', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ea7a5103-8446-473a-a3bc-a70025ad070b'	System	24 Sep 2020 03:28:03
User entered 'None (0)'	System	24 Sep 2020 03:28:03

FDA-CBER-2022-1614-0647779

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:45', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ea7a5103-8446-473a-a3bc-a70025ad070b'	System	24 Sep 2020 03:28:03
User entered 'None (0)'	System	24 Sep 2020 03:28:03

FDA-CBER-2022-1614-0647780

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:49', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ea7a5103-8446-473a-a3bc-a70025ad070b'	System	24 Sep 2020 03:28:03
User entered 'None (0)'	System	24 Sep 2020 03:28:03

FDA-CBER-2022-1614-0647781

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:51', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ea7a5103-8446-473a-a3bc-a70025ad070b'	System	24 Sep 2020 03:28:03
User entered 'None (0)'	System	24 Sep 2020 03:28:03

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:54', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ea7a5103-8446-473a-a3bc-a70025ad070b'	System	24 Sep 2020 03:28:03
User entered 'None (0)'	System	24 Sep 2020 03:28:03

FDA-CBER-2022-1614-0647783

US3232048

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:27:57', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ea7a5103-8446-473a-a3bc-a70025ad070b'	System	24 Sep 2020 03:28:03
User entered 'No (N)'	System	24 Sep 2020 03:28:03

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-23T22:28:00', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'ea7a5103-8446-473a-a3bc-a70025ad070b'	System	24 Sep 2020 03:28:03
User entered '23 Sep 2020 22:28'	System	24 Sep 2020 03:28:03

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647786

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647787

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	18 Sep 2020 16:46:08
User entered 'Day 7'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647788

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:09:59', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'f3dae0d3-64db-40b4-8e6e-8a2a85f440b8'	System	25 Sep 2020 00:10:20
User entered 'None (0)'	System	25 Sep 2020 00:10:20

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:10:01', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'f3dae0d3-64db-40b4-8e6e-8a2a85f440b8'	System	25 Sep 2020 00:10:20
User entered 'None (0)'	System	25 Sep 2020 00:10:20

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:10:03', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'f3dae0d3-64db-40b4-8e6e-8a2a85f440b8'	System	25 Sep 2020 00:10:20
User entered 'None (0)'	System	25 Sep 2020 00:10:20

FDA-CBER-2022-1614-0647791

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:10:05', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'f3dae0d3-64db-40b4-8e6e-8a2a85f440b8'	System	25 Sep 2020 00:10:20
User entered 'None (0)'	System	25 Sep 2020 00:10:20

FDA-CBER-2022-1614-0647792

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:10:07', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'f3dae0d3-64db-40b4-8e6e-8a2a85f440b8'	System	25 Sep 2020 00:10:20
User entered 'None (0)'	System	25 Sep 2020 00:10:20

FDA-CBER-2022-1614-0647793

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:10:09', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'f3dae0d3-64db-40b4-8e6e-8a2a85f440b8'	System	25 Sep 2020 00:10:20
User entered 'None (0)'	System	25 Sep 2020 00:10:20

FDA-CBER-2022-1614-0647794

US3232048

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:10:13', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'f3dae0d3-64db-40b4-8e6e-8a2a85f440b8'	System	25 Sep 2020 00:10:20
User entered 'No (N)'	System	25 Sep 2020 00:10:20

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-09-24T19:10:15', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'f3dae0d3-64db-40b4-8e6e-8a2a85f440b8'	System	25 Sep 2020 00:10:20
User entered '24 Sep 2020 19:10'	System	25 Sep 2020 00:10:20

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647797

US3232048
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:04:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:46:08

FDA-CBER-2022-1614-0647798

US3232048
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	25 Sep 2020 22:41:42

FDA-CBER-2022-1614-0647799

US3232048
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '25 Sep 2020'	Jerrica Sullivan (b) (4) (b) (4)	25 Sep 2020 22:41:42

FDA-CBER-2022-1614-0647800

US3232048
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4) (b) (4)	25 Sep 2020 22:41:42

US3232048
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	25 Sep 2020 22:41:42

FDA-CBER-2022-1614-0647802

US3232048
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	25 Sep 2020 22:41:49

FDA-CBER-2022-1614-0647803

US3232048
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '1'	System	25 Sep 2020 22:41:49

FDA-CBER-2022-1614-0647804

US3232048
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	05 Oct 2020 16:31:58

FDA-CBER-2022-1614-0647805

US3232048
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '2 Oct 2020'	Adreanna Pou (b) (4) (b) (4)	05 Oct 2020 16:31:58

FDA-CBER-2022-1614-0647806

US3232048
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4) (b) (4)	05 Oct 2020 16:31:58

US3232048
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	05 Oct 2020 16:31:58

FDA-CBER-2022-1614-0647808

US3232048
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	05 Oct 2020 16:32:03

FDA-CBER-2022-1614-0647809

US3232048
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '1'	System	05 Oct 2020 16:32:03

FDA-CBER-2022-1614-0647810

US3232048
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:32:43

FDA-CBER-2022-1614-0647811

US3232048
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '9 Oct 2020'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:32:43

FDA-CBER-2022-1614-0647812

US3232048
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:32:43

FDA-CBER-2022-1614-0647813

US3232048
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:32:43

FDA-CBER-2022-1614-0647814

US3232048
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:32:37

FDA-CBER-2022-1614-0647815

US3232048
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '1'	System	09 Oct 2020 20:32:37

FDA-CBER-2022-1614-0647816

US3232048
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:10:36

FDA-CBER-2022-1614-0647817

US3232048
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '16 Oct 2020'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:10:36

FDA-CBER-2022-1614-0647818

US3232048
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:10:36

FDA-CBER-2022-1614-0647819

US3232048
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:04:06
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'VISIT3'	System	16 Oct 2020 17:10:36

FDA-CBER-2022-1614-0647820

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647821

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '16 Oct 2020'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647822

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '10:40'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647823

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '16 Oct 2020 10:40'	System	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647824

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '98.3' F	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647825

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (Oral)'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647826

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647827

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '66'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647828

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'bpm'	System	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647829

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '24'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647830

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'breaths/min'	System	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647831

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '126'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647832

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'mmHg'	System	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647833

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '84'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647834

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered 'mmHg'	System	16 Oct 2020 17:12:28

FDA-CBER-2022-1614-0647835

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15

FDA-CBER-2022-1614-0647836

US3232048
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:04:06
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15

FDA-CBER-2022-1614-0647837

US3232048
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:04:06
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:46

FDA-CBER-2022-1614-0647838

US3232048
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:04:06
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '16 Oct 2020'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:12:46

FDA-CBER-2022-1614-0647839

US3232048
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:13:18

FDA-CBER-2022-1614-0647840

US3232048
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '16 Oct 2020'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:13:18

FDA-CBER-2022-1614-0647841

US3232048
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '11:00'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:13:18

FDA-CBER-2022-1614-0647842

US3232048
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:04:06
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '16 Oct 2020 11:00'	System	16 Oct 2020 17:13:18

FDA-CBER-2022-1614-0647843

US3232048
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	16 Oct 2020 17:13:23

FDA-CBER-2022-1614-0647844

US3232048
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '1'	System	16 Oct 2020 17:13:23

FDA-CBER-2022-1614-0647845

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 64'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647846

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-10-22T06:34:03', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c105fa4c-36de-454f-b8ab-26b1dc494646'	System	22 Oct 2020 11:34:16
User entered 'No (N)'	System	22 Oct 2020 11:34:16

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-10-22T06:34:10', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c105fa4c-36de-454f-b8ab-26b1dc494646'	System	22 Oct 2020 11:34:16
User entered 'No (N)'	System	22 Oct 2020 11:34:16

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-10-22T06:34:13', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: 'c105fa4c-36de-454f-b8ab-26b1dc494646'	System	22 Oct 2020 11:34:16
User entered '22 Oct 2020 06:34:13'	System	22 Oct 2020 11:34:16

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647850

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647851

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 71'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647852

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-10-28T17:11:43', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '886f1e38-3b0f-4857-a2aa-cd9d96c672ae'	System	28 Oct 2020 22:11:55
User entered 'No (N)'	System	28 Oct 2020 22:11:55

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-10-28T17:11:49', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '886f1e38-3b0f-4857-a2aa-cd9d96c672ae'	System	28 Oct 2020 22:11:55
User entered 'No (N)'	System	28 Oct 2020 22:11:55

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-10-28T17:11:53', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '886f1e38-3b0f-4857-a2aa-cd9d96c672ae'	System	28 Oct 2020 22:11:55
User entered '28 Oct 2020 17:11:53'	System	28 Oct 2020 22:11:55

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647856

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647857

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 78'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647858

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-11-04T07:49:48', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '2342c7fd-9996-49e6-973d-79059dd20bc4'	System	04 Nov 2020 13:49:56
User entered 'No (N)'	System	04 Nov 2020 13:49:56

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-11-04T07:49:51', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '2342c7fd-9996-49e6-973d-79059dd20bc4'	System	04 Nov 2020 13:49:56
User entered 'No (N)'	System	04 Nov 2020 13:49:56

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-11-04T07:49:54', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '2342c7fd-9996-49e6-973d-79059dd20bc4'	System	04 Nov 2020 13:49:56
User entered '04 Nov 2020 07:49:54'	System	04 Nov 2020 13:49:56

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647862

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647863

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 92'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647864

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-11-18T09:38:58', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '5768d10b-6a79-4cf2-be5a-5f00773761ee'	System	18 Nov 2020 15:39:10
User entered 'No (N)'	System	18 Nov 2020 15:39:10

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-11-18T09:39:04', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '5768d10b-6a79-4cf2-be5a-5f00773761ee'	System	18 Nov 2020 15:39:10
User entered 'No (N)'	System	18 Nov 2020 15:39:10

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-11-18T09:39:07', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '5768d10b-6a79-4cf2-be5a-5f00773761ee'	System	18 Nov 2020 15:39:10
User entered '18 Nov 2020 09:39:07'	System	18 Nov 2020 15:39:10

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647868

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647869

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:39
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 99'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647870

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-11-28T09:07:52', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '01a2d44b-aca6-47b5-b780-145c56a6591b'	System	28 Nov 2020 15:07:59
User entered 'No (N)'	System	28 Nov 2020 15:07:59
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:39
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-11-28T09:07:54', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '01a2d44b-aca6-47b5-b780-145c56a6591b'	System	28 Nov 2020 15:07:59
User entered 'No (N)'	System	28 Nov 2020 15:07:59
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:39
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-11-28T09:07:57', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '01a2d44b-aca6-47b5-b780-145c56a6591b'	System	28 Nov 2020 15:07:59
User entered '28 Nov 2020 09:07:57'	System	28 Nov 2020 15:07:59
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:39
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09

FDA-CBER-2022-1614-0647873

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:39
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '25 Nov 2020 00:01'	System	21 Aug 2020 16:28:01

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:39
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '29 Nov 2020 23:59'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647875

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:45
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09
Data entry locked.	System	21 Aug 2020 16:28:01
User entered 'Day 106'	System	21 Aug 2020 16:28:01

FDA-CBER-2022-1614-0647876

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-12-02T16:22:15', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '635f7a52-394b-4946-8dc7-803c498a541f'	System	02 Dec 2020 22:22:22
User entered 'No (N)'	System	02 Dec 2020 22:22:22
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:45
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09

US3232048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-12-02T16:22:18', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '635f7a52-394b-4946-8dc7-803c498a541f'	System	02 Dec 2020 22:22:22
User entered 'No (N)'	System	02 Dec 2020 22:22:22
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:45
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-12-02T16:22:21', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '635f7a52-394b-4946-8dc7-803c498a541f'	System	02 Dec 2020 22:22:22
User entered '02 Dec 2020 16:22:21'	System	02 Dec 2020 22:22:22
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:45
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:45
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '02 Dec 2020 00:01'	System	21 Aug 2020 16:28:01

US3232048
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:07
DataPoint activated with code reason code Data required.	Jerrica Sullivan (b) (4) (b) (4)	19 Nov 2020 21:37:45
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:09
Data entry locked.	System	21 Aug 2020 16:28:01
User entered '06 Dec 2020 23:59'	System	21 Aug 2020 16:28:01

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:09
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 07:12:09

FDA-CBER-2022-1614-0647882

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647887

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647888

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647889

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647890

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647891

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647892

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647893

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647894

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647895

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647896

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647897

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647898

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647899

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647900

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647901

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647902

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647903

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647907

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:09
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:12:09

FDA-CBER-2022-1614-0647908

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:09
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:12:09

FDA-CBER-2022-1614-0647909

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:09
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:12:09

FDA-CBER-2022-1614-0647910

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-12-02T16:22:04', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '737b6983-0305-4620-803a-2e9fe34aa529'	System	02 Dec 2020 22:22:15
User entered 'No (N)'	System	02 Dec 2020 22:22:15

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-12-02T16:22:08', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '737b6983-0305-4620-803a-2e9fe34aa529'	System	02 Dec 2020 22:22:15
User entered 'No (N)'	System	02 Dec 2020 22:22:15

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F17E867-94D3-461B-9A98-169889250615)', Time: '2020-12-02T16:22:11', User OID: 'PatientReportedOutcome (US3232048)', ODM File OID: '737b6983-0305-4620-803a-2e9fe34aa529'	System	02 Dec 2020 22:22:15
User entered '02 Dec 2020 16:22:11'	System	02 Dec 2020 22:22:15

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:09
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:12:09

FDA-CBER-2022-1614-0647914

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:09
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:12:09

FDA-CBER-2022-1614-0647915

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:09
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:12:09

FDA-CBER-2022-1614-0647916

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647921

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647922

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647923

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647924

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647925

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647926

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647927

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647928

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647929

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647930

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647931

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647932

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647933

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647934

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647935

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647936

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647937

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	02 May 2021 13:47:27

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647941

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:09
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:12:09

FDA-CBER-2022-1614-0647942

US3232048
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:04:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:09
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:12:09

FDA-CBER-2022-1614-0647943

US3232048
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	13 Nov 2020 21:10:32

FDA-CBER-2022-1614-0647944

US3232048
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '13 Nov 2020'	Jerrica Sullivan (b) (4) (b) (4)	13 Nov 2020 21:10:32

FDA-CBER-2022-1614-0647945

US3232048
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4) (b) (4)	13 Nov 2020 21:10:32

US3232048
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	13 Nov 2020 21:10:32

FDA-CBER-2022-1614-0647947

US3232048
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	13 Nov 2020 21:10:40

FDA-CBER-2022-1614-0647948

US3232048
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 04:43:15
User entered '1'	System	13 Nov 2020 21:10:40

FDA-CBER-2022-1614-0647949

US3232048
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:49:53
Signature has been broken.	Adreanna Pou (b) (4) (b) (4)	08 Mar 2021 20:43:08
User entered 'No (N)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	08 Mar 2021 20:43:08
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 13:44:34
Query 'Data is required. Please complete.' answered with 'entered by mistake' (Site from System).	Adreanna Pou (b) (4) (b) (4)	17 Feb 2021 17:36:17
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 17:35:56
User entered empty.	Adreanna Pou (b) (4) (b) (4)	17 Feb 2021 17:35:56

US3232048
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	17 Feb 2021 17:35:56

US3232048
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	17 Feb 2021 17:35:56

FDA-CBER-2022-1614-0647952

US3232048
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:04:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:49:53
Signature has been broken.	Adreanna Pou (b) (4) (b) (4)	08 Mar 2021 20:43:08
User entered 'Subject passed away on December 12, 2020.' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	08 Mar 2021 20:43:08
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	17 Feb 2021 17:35:56

US3232048
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:49:53
User entered 'No (N)'	Adreanna Pou (b) (4) (b) (4)	08 Mar 2021 20:42:13

FDA-CBER-2022-1614-0647954

US3232048
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:04:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered empty.	System	08 Mar 2021 20:42:13

FDA-CBER-2022-1614-0647955

US3232048
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 16:04:06
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:26:33

FDA-CBER-2022-1614-0647956

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:20:44
User entered 'USA-US105-2020-mRNA-1273-P301000003'	System	11 Dec 2020 15:20:16
User entered 'New'	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0647957

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User coded data point as SOC: Nervous system disorders, HLGT: Neuromuscular disorders, HLT: Motor neurone diseases, PT: Amyotrophic lateral sclerosis, LLT: Amyotrophic lateral sclerosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 08:52:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 08:52:55
Data point term sent to Coder	System	16 Mar 2021 20:34:25
User closed query 'For coding purposes, for term COMPLICATION OF AMYOTROPHIC LATERAL SCLEROSIS please specify the complication and update the term with your response.' (Site from System).	System	16 Mar 2021 20:33:41
Query 'For coding purposes, for term COMPLICATION OF AMYOTROPHIC LATERAL SCLEROSIS please specify the complication and update the term with your response.' answered with 'confirm correct as entered, per death certificate' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	16 Mar 2021 20:33:41
User opened query 'For coding purposes, for term COMPLICATION OF AMYOTROPHIC LATERAL SCLEROSIS please specify the complication and update the term with your response.' (Site from System).	Coder Import (b) (4) (b) (4)	16 Mar 2021 16:36:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:49:53
Data point term sent to Coder	System	11 Mar 2021 17:15:06
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 17:14:49
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 17:14:49
User entered 'complication OF AMYOTROPHIC LATERAL SCLEROSIS' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 17:14:49
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48

FDA-CBER-2022-1614-0647958

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Adverse event

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this worsening event and please note, there is no baseline MH or prior AE record that would support this worsening condition. Please review and update to record the baseline MH or prior AE as applicable or consider to remove the term Progression. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 09:40:14
Query 'Per DM CLR: Please review this worsening event and please note, there is no baseline MH or prior AE record that would support this worsening condition. Please review and update to record the baseline MH or prior AE as applicable or consider to remove the term Progression. Otherwise, clarify.' answered with 'ALS is listed in MH. ALS is a progressive disease that is terminal ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 13:41:50
User opened query 'Per DM CLR: Please review this worsening event and please note, there is no baseline MH or prior AE record that would support this worsening condition. Please review and update to record the baseline MH or prior AE as applicable or consider to remove the term Progression. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 12:22:07
User coded data point as SOC: Nervous system disorders, HLGT: Neuromuscular disorders, HLT: Motor neurone diseases, PT: Amyotrophic lateral sclerosis, LLT: Amyotrophic lateral sclerosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:53:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:53:58
Data point term sent to Coder	System	10 Dec 2020 16:34:36
User entered 'progression of Amyotrophic lateral sclerosis'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647959

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647960

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647961

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647962

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '05 Nov 2020'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647963

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647964

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered empty.	System	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647965

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 14:57:29
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Dec 2020 14:57:29
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	17 Dec 2020 14:57:29
User entered '12 Dec 2020' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 14:57:29
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Dec 2020 14:56:45
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647967

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	17 Dec 2020 14:57:45
User entered empty; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 14:57:45
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	17 Dec 2020 14:57:29
User entered '2:00' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 14:57:29
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647968

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Dec 2020 20:42:49
User entered empty.	System	17 Dec 2020 14:57:45
User entered '12 Dec 2020 2:00'	System	17 Dec 2020 14:57:29
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Dec 2020 14:50:28
User entered empty.	System	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647969

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	17 Dec 2020 14:57:29
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 14:57:29
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	17 Dec 2020 14:56:45
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'PV Query: As the outcome was reported as fatal, please consider adding seriousness criteria of death' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:36:11
Query 'PV Query: As the outcome was reported as fatal, please consider adding seriousness criteria of death' answered with 'updated to include death' (Site from Safety).	Adreanna Pou (b) (4) (b) (4)	22 Dec 2020 16:01:30
User entered '1' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	22 Dec 2020 16:01:12
User opened query 'PV Query: As the outcome was reported as fatal, please consider adding seriousness criteria of death' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 13:51:44
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647972

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647973

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647974

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647975

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647976

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647977

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647978

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647979

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647980

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	12 Dec 2020 15:29:31
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

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US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	12 Dec 2020 15:29:31
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'PV Query: Please consider updating the action taken with study drug to not applicable as per source, subject received both doses of study drug.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Dec 2020 20:54:58
Query 'PV Query: Please consider updating the action taken with study drug to not applicable as per source, subject received both doses of study drug.' answered with 'corrected' (Site from Safety).	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 14:47:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 14:47:19
User opened query 'PV Query: Please consider updating the action taken with study drug to not applicable as per source, subject received both doses of study drug.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Dec 2020 14:51:05
User entered 'None (NONE)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	26 Mar 2021 14:10:08
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:37:57
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

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US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

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US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Dec 2020 20:55:02
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated that the condition was fatal.' (Site from Safety).	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 16:59:33
User entered 'Fatal (FATAL)' reason for change: New Information	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 14:56:45
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Dec 2020 14:50:07
User entered 'Unknown (UNKNOWN)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

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US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Jan 2021 19:33:50
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Jan 2021 19:33:41
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'subjects wife did not request autopsy ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 14:12:12
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'cause of death amyotrophic lateral sclerosis ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	06 Jan 2021 14:11:58
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Dec 2020 15:01:02
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Dec 2020 15:00:48
Query 'PV Query: Please provide any treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Dec 2020 20:42:53
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:36:31
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:36:23
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'medical records pending' (Site from Safety).	Adreanna Pou (b) (4) (b) (4)	22 Dec 2020 17:42:39
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'medical records pending' (Site from Safety).	Adreanna Pou (b) (4) (b) (4)	22 Dec 2020 17:42:29

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 13:51:23
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 13:51:02
User opened query 'PV Query: Please provide any treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 13:50:19
User closed query 'PV Query: Please provide details on the specific signs and symptoms of the disease that aggravated.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Dec 2020 20:55:15
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Dec 2020 20:55:12
User closed query 'PV Query: Please provide any treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Dec 2020 20:55:06
Query 'PV Query: Please provide details on the specific signs and symptoms of the disease that aggravated.' answered with 'Chronic progression of ALS.' (Site from Safety).	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 17:19:39
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'Patient was tested for covid on September 4, 2020 from his primary care doctor and the results of the test were negative.' (Site from Safety).	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 17:19:17

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Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 16:59:38
User entered 'Patient was placed in hospice on November 19, 2020 in home secondary to dysphagia with peg tube placement and progression of ALS. Patient died at home on December 12, 2020 at 2 am. Pending death certificate for cause of death.' reason for change: New Information	Adreanna Pou (b) (4) (b) (4)	17 Dec 2020 14:56:45
User opened query 'PV Query: Please provide details on the specific signs and symptoms of the disease that aggravated.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Dec 2020 14:51:34
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Dec 2020 14:51:22
User opened query 'PV Query: Please provide any treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Dec 2020 14:50:48
User entered 'patient was placed hospice care 19Nov2020'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:33:53

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '1'	System	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647993

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '1'	System	10 Dec 2020 16:33:53

FDA-CBER-2022-1614-0647994

US3232048
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:04:06
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647995

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0647996

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Dysphagia, LLT: Dysphagia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 16:38:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 16:38:51
Data point term sent to Coder	System	10 Dec 2020 16:37:42
User entered 'dysphagia'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0647997

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0647998

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0647999

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648000

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '10 Dec 2020'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648001

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648002

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered empty.	System	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648003

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648004

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648005

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648006

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered empty.	System	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648007

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648009

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648010

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648011

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648012

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648013

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648014

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648015

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648016

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648017

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648018

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648019

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648020

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'None (NONE)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648022

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648023

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648024

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the treatment procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Jan 2021 09:20:50
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the treatment procedure as appropriate. Otherwise, clarify.' answered with 'cp page updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	19 Jan 2021 13:52:53
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the treatment procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 12:21:49
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648026

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648027

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'patient received percutaneous endoscopic gastrostomy tube'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648028

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '0'	System	10 Dec 2020 16:37:33

FDA-CBER-2022-1614-0648029

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '1'	System	10 Dec 2020 16:37:33

US3232048
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:04:06
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27

FDA-CBER-2022-1614-0648031

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04

FDA-CBER-2022-1614-0648032

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:38:49
User coded data point as SOC: Gastrointestinal disorders, HLGT: Salivary gland conditions, HLT: Oral dryness and saliva altered, PT: Salivary hypersecretion, LLT: Saliva secretion increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 20:38:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 20:38:23
Data point term sent to Coder	System	30 Mar 2021 13:56:59
User closed query 'For coding purposes, please specify if SALIVARY SECRETIONS are Saliva secretion decreased, Saliva secretion increased or something else. Please update the term with your response' (Site from System).	System	30 Mar 2021 13:56:26
Query 'For coding purposes, please specify if SALIVARY SECRETIONS are Saliva secretion decreased, Saliva secretion increased or something else. Please update the term with your response' answered with 'updated' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 13:56:26
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 13:56:11
User entered 'increased SALIVARY SECRETIONS' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 13:56:11
User opened query 'For coding purposes, please specify if SALIVARY SECRETIONS are Saliva secretion decreased, Saliva secretion increased or something else. Please update the term with your response' (Site from System).	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:08:15
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	26 Mar 2021 14:10:08
Data point term sent to Coder	System	22 Mar 2021 18:39:25
User closed query 'CDM Coding: Please clarify this clinical event (SECRETIONS) with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g Wound secretion, Salivary hypersecretion etc)' (Site from System).	System	22 Mar 2021 18:38:42

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Adverse event

Audit	User	Time (GMT)
Query 'CDM Coding: Please clarify this clinical event (SECRETIONS) with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g Wound secretion, Salivary hypersecretion etc)' answered with 'UPDATED' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:38:42
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:38:27
User entered 'sALIVARY SECRETIONS' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:38:27
User opened query 'CDM Coding: Please clarify this clinical event (SECRETIONS) with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g Wound secretion, Salivary hypersecretion etc)' (Site from System).	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:42:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Data point term sent to Coder	System	19 Feb 2021 17:17:09
User entered 'secretions'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648036

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '23 Sep 2020'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648038

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648039

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User entered empty.	System	19 Feb 2021 17:16:32

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648041

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Per CDM: Please verify that AE end date is recorded however outcome provided as "Not Recovered/Not Resolved". Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Feb 2021 08:17:33
Query 'Per CDM: Please verify that AE end date is recorded however outcome provided as "Not Recovered/Not Resolved". Please review and update accordingly. Else clarify.' answered with 'end date is date of death' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 18:18:13
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 09:18:35
User opened query 'Per CDM: Please verify that AE end date is recorded however outcome provided as "Not Recovered/Not Resolved". Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 09:18:33
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'patient is deceased' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:17:37
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	19 Feb 2021 17:17:13
User entered '12 Dec 2020'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648042

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648043

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User entered empty.	System	19 Feb 2021 17:16:32

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Feb 2021 17:16:47
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	19 Feb 2021 17:16:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648046

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648047

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648048

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648049

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648050

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648051

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648052

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648053

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648054

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648055

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648056

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648057

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648058

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'None (NONE)'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648060

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648061

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648062

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 17:17:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 17:17:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:17:13
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 17:16:47
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:47
User entered 'Fatal (FATAL)'	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648065

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User entered '0'	System	19 Feb 2021 17:16:32

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04
User entered '0'	System	19 Feb 2021 17:16:32

FDA-CBER-2022-1614-0648067

US3232048
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:04:06
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 12:52:04

FDA-CBER-2022-1614-0648068

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:04:06

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:44:32
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:11:55

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:19:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:19:38
Data point term sent to Coder	System	24 Aug 2020 14:45:28
User entered 'asorbic acid'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 12:23:55
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	01 Mar 2021 13:53:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	01 Mar 2021 13:53:11
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 12:36:46
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'maintenance'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

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US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '500'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

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US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

FDA-CBER-2022-1614-0648074

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

FDA-CBER-2022-1614-0648075

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

FDA-CBER-2022-1614-0648077

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

FDA-CBER-2022-1614-0648078

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

FDA-CBER-2022-1614-0648079

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'un UNK 2019'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

FDA-CBER-2022-1614-0648080

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

FDA-CBER-2022-1614-0648081

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:18:12
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:18:12
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

FDA-CBER-2022-1614-0648083

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:09

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '1'	System	24 Aug 2020 14:45:09

FDA-CBER-2022-1614-0648085

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '1'	System	24 Aug 2020 14:45:09

FDA-CBER-2022-1614-0648086

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '804 (804)'	System	24 Aug 2020 14:45:09

FDA-CBER-2022-1614-0648087

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:08:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:08:35
Data point term sent to Coder	System	24 Sep 2020 17:03:49
Coding entries removed.	Adreanna Pou (b) (4) (b) (4)	24 Sep 2020 17:03:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:47:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:47:40
Data point term sent to Coder	System	24 Aug 2020 14:46:29
User entered 'ASA'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:06

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Oct 2020 18:12:57
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate. ' answered with 'UPDATED PER QUERY RESOLUTION' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	24 Sep 2020 17:03:12
User entered 'CARDIAC PROPHYLACTIC' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	24 Sep 2020 17:03:07
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 10:25:02
User entered 'prophylactic'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '81'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

FDA-CBER-2022-1614-0648093

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

FDA-CBER-2022-1614-0648095

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

FDA-CBER-2022-1614-0648096

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

FDA-CBER-2022-1614-0648097

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '14 Apr 2016'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

FDA-CBER-2022-1614-0648098

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

FDA-CBER-2022-1614-0648099

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:18:23
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:18:23
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:45:39

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:29
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:45:39

FDA-CBER-2022-1614-0648103

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:29
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:45:39

FDA-CBER-2022-1614-0648104

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:29
User entered '804 (804)'	(b) (4), (b) (6) System	24 Aug 2020 14:45:39

FDA-CBER-2022-1614-0648105

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:47:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:47:40
Data point term sent to Coder	System	24 Aug 2020 14:46:30
User entered 'carvedilol'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

FDA-CBER-2022-1614-0648107

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'hypertension'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

FDA-CBER-2022-1614-0648108

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '25'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

FDA-CBER-2022-1614-0648109

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

FDA-CBER-2022-1614-0648111

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

FDA-CBER-2022-1614-0648113

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

FDA-CBER-2022-1614-0648114

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

FDA-CBER-2022-1614-0648115

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '17 Dec 2019'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

FDA-CBER-2022-1614-0648117

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:18:41
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:18:41
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:53
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:46:13

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:53
User entered '2'	(b) (4), (b) (6) System	24 Aug 2020 14:46:13

FDA-CBER-2022-1614-0648121

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:53
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:46:13

FDA-CBER-2022-1614-0648122

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:53
	(b) (4), (b) (6)	
User entered '804 (804)'	System	24 Aug 2020 14:46:13

FDA-CBER-2022-1614-0648123

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
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: CHOLECALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 05:53:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 05:53:03
Data point term sent to Coder	System	24 Aug 2020 14:47:33
User entered 'cholecoleficerol'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:06

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 12:24:12
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	01 Mar 2021 13:53:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	01 Mar 2021 13:53:40
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 12:37:05
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'maintenance'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

FDA-CBER-2022-1614-0648126

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '1000'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:49:53
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 16:14:45
User entered 'IU (IU)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 16:14:45
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Other (OTHER)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:49:53
User closed query 'Per DM CLR: Please review the unit and verify if IU is more appropriate for the given dose. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 12:42:57
Query 'Per DM CLR: Please review the unit and verify if IU is more appropriate for the given dose. Review and update as applicable. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 16:14:53
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 16:14:45
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 16:14:45
User opened query 'Per DM CLR: Please review the unit and verify if IU is more appropriate for the given dose. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 07:55:54
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'units'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

FDA-CBER-2022-1614-0648131

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

FDA-CBER-2022-1614-0648132

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

FDA-CBER-2022-1614-0648133

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 May 2020'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

FDA-CBER-2022-1614-0648134

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

FDA-CBER-2022-1614-0648135

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:18:55
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:18:55
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:47:28

FDA-CBER-2022-1614-0648138

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:01
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:47:28

FDA-CBER-2022-1614-0648139

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:01
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:47:28

FDA-CBER-2022-1614-0648140

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:01
User entered '804 (804)'	(b) (4), (b) (6) System	24 Aug 2020 14:47:28

FDA-CBER-2022-1614-0648141

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: GUANFACINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:13:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:13:33
Data point term sent to Coder	System	24 Aug 2020 14:48:35
User entered 'guanfacine'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

FDA-CBER-2022-1614-0648143

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'hypertension'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

FDA-CBER-2022-1614-0648144

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '.5'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

FDA-CBER-2022-1614-0648147

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

FDA-CBER-2022-1614-0648149

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

FDA-CBER-2022-1614-0648150

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

FDA-CBER-2022-1614-0648151

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '6 Dec 2019'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

FDA-CBER-2022-1614-0648153

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:19:13
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Feb 2021 17:19:25
User entered '12 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:19:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Feb 2021 17:19:13
User entered '12 2020' (non-conformant).	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:19:13
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:17

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:13
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:48:17

FDA-CBER-2022-1614-0648157

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:13
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:48:17

FDA-CBER-2022-1614-0648158

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:13
	(b) (4), (b) (6)	
User entered '804 (804)'	System	24 Aug 2020 14:48:17

FDA-CBER-2022-1614-0648159

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:53:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:53:40
Data point term sent to Coder	System	24 Aug 2020 14:49:36
User entered 'magnesium'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 12:24:21
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	01 Mar 2021 13:54:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	01 Mar 2021 13:54:00
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 12:37:25
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'maintenance'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648162

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '235'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648163

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648165

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648167

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648168

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648169

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '3 Mar 2020'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648170

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648171

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:20:01
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:20:01
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648173

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:43
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:48:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:43
User entered '2'	(b) (4), (b) (6) System	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648175

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:43
	(b) (4), (b) (6)	
User entered '1'	System	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648176

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:43
	(b) (4), (b) (6)	
User entered '804 (804)'	System	24 Aug 2020 14:48:58

FDA-CBER-2022-1614-0648177

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:50:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:50:34
Data point term sent to Coder	System	24 Aug 2020 14:49:36
User entered 'multivitamin'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 12:24:27
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	01 Mar 2021 13:54:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	01 Mar 2021 13:54:24
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 12:37:44
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'maintenance'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

FDA-CBER-2022-1614-0648180

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'tablet (TABLET)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

FDA-CBER-2022-1614-0648182

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

FDA-CBER-2022-1614-0648185

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

FDA-CBER-2022-1614-0648186

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

FDA-CBER-2022-1614-0648187

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '3 Mar 2020'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

FDA-CBER-2022-1614-0648188

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

FDA-CBER-2022-1614-0648189

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:22:05
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:22:05
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:56
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:49:33

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:56
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:49:33

FDA-CBER-2022-1614-0648193

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:56
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:49:33

FDA-CBER-2022-1614-0648194

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:56
User entered '804 (804)'	(b) (4), (b) (6) System	24 Aug 2020 14:49:33

FDA-CBER-2022-1614-0648195

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:23:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:23:40
Data point term sent to Coder	System	24 Aug 2020 14:50:40
User entered 'probiotic'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 12:24:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	01 Mar 2021 13:54:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	01 Mar 2021 13:54:45
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 12:38:13
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'maintenance'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'capsule (CAPSULE)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

FDA-CBER-2022-1614-0648200

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

FDA-CBER-2022-1614-0648201

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

FDA-CBER-2022-1614-0648203

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

FDA-CBER-2022-1614-0648204

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '3 Mar 2020'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

FDA-CBER-2022-1614-0648206

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

FDA-CBER-2022-1614-0648207

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:24:58
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:24:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

FDA-CBER-2022-1614-0648209

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:13
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:15

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:13
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:50:15

FDA-CBER-2022-1614-0648211

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:13
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:50:15

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:13
User entered '804 (804)'	(b) (4), (b) (6) System	24 Aug 2020 14:50:15

FDA-CBER-2022-1614-0648213

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:52:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:52:37
Data point term sent to Coder	System	24 Aug 2020 14:51:42
User entered 'quetiapine'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

FDA-CBER-2022-1614-0648215

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'insomnia'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '25'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

FDA-CBER-2022-1614-0648217

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

FDA-CBER-2022-1614-0648219

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

FDA-CBER-2022-1614-0648222

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '4 Feb 2020'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:25:24
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:25:24
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:50:58

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:48
	(b) (4), (b) (6)	
User entered '1'	System	24 Aug 2020 14:50:58

FDA-CBER-2022-1614-0648229

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:48
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:50:58

FDA-CBER-2022-1614-0648230

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:54:48
User entered '804 (804)'	(b) (4), (b) (6) System	24 Aug 2020 14:50:58

FDA-CBER-2022-1614-0648231

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: RILUZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:19:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:19:35
Data point term sent to Coder	System	24 Aug 2020 14:51:42
User entered 'riluzole'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'ALS'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648234

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '50'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648235

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648237

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648238

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648239

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648240

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648241

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '17 Dec 2019'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648242

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:25:34
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:25:34
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648246

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:23
User entered '2'	(b) (4), (b) (6) System	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648247

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:23
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648248

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:23
	(b) (4), (b) (6)	
User entered '804 (804)'	System	24 Aug 2020 14:51:32

FDA-CBER-2022-1614-0648249

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE INACT SPLIT 3V, PRODUCTSYNONYM: FLUZONE HIGH DOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:58:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:58:39
Data point term sent to Coder	System	09 Oct 2020 20:34:00
User entered 'fluzone high dose'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

FDA-CBER-2022-1614-0648251

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'influenza vaccine'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

FDA-CBER-2022-1614-0648252

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '.5'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'mL (mL)'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

FDA-CBER-2022-1614-0648255

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'once (ONCE)'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

FDA-CBER-2022-1614-0648256

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

FDA-CBER-2022-1614-0648257

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

FDA-CBER-2022-1614-0648259

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '2 Oct 2020'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

FDA-CBER-2022-1614-0648260

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

FDA-CBER-2022-1614-0648261

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '2 Oct 2020'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:55:04
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	09 Oct 2020 20:33:56

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:04
User entered empty.	(b) (4), (b) (6) System	09 Oct 2020 20:33:56

FDA-CBER-2022-1614-0648265

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:04
User entered empty.	(b) (4), (b) (6) System	09 Oct 2020 20:33:56

FDA-CBER-2022-1614-0648266

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:55:04
User entered empty.	(b) (4), (b) (6) System	09 Oct 2020 20:33:56

FDA-CBER-2022-1614-0648267

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: BELLADONNA AND DERIVATIVES, PLAIN, ATC: BELLADONNA ALKALOIDS, TERTIARY AMINES, PRODUCT: HYOSCYAMINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 17:26:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 17:26:52
Data point term sent to Coder	System	19 Feb 2021 17:26:23
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:26:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: BELLADONNA AND DERIVATIVES, PLAIN, ATC: BELLADONNA ALKALOIDS, TERTIARY AMINES, PRODUCT: HYOSCYAMINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 23:52:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 23:52:27
Data point term sent to Coder	System	29 Jan 2021 13:43:53
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 13:43:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: BELLADONNA AND DERIVATIVES, PLAIN, ATC: BELLADONNA ALKALOIDS, TERTIARY AMINES, PRODUCT: HYOSCYAMINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:25:49

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:06

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:25:49
Data point term sent to Coder	System	10 Dec 2020 16:39:45
User entered 'hycosarmine sulfate'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

FDA-CBER-2022-1614-0648270

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:06

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'SECRETIONS' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:26:20
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Feb 2021 11:28:15
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 13:43:11
User entered 'SECRETIONS (dysphagia)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 13:43:05
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 05:05:29
User entered 'secretions'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '.125'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

FDA-CBER-2022-1614-0648272

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

FDA-CBER-2022-1614-0648274

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'as needed (PRN)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

FDA-CBER-2022-1614-0648276

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Other (OTHER)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

FDA-CBER-2022-1614-0648277

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'sublingual'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

FDA-CBER-2022-1614-0648278

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '23 Sep 2020'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

FDA-CBER-2022-1614-0648279

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 10:59:07
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'updated ae log to indicate secretions with start date' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:26:08
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Feb 2021 22:45:54
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:25:51
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

US3232048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Dec 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Feb 2021 17:25:51
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 12:53:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 16:39:23

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:38
User entered empty.	(b) (4), (b) (6) System	10 Dec 2020 16:39:23

FDA-CBER-2022-1614-0648284

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:38
User entered empty.	(b) (4), (b) (6) System	10 Dec 2020 16:39:23

FDA-CBER-2022-1614-0648285

US3232048
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:04:06
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:53:38
User entered empty.	(b) (4), (b) (6) System	10 Dec 2020 16:39:23

FDA-CBER-2022-1614-0648286

US3232048
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 16:04:06
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Jan 2021 13:51:20
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	21 Aug 2020 20:12:01

US3232048
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:04:06
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '10 Dec 2020'	Jerrica Sullivan (b) (4) (b) (4)	19 Jan 2021 13:52:34

FDA-CBER-2022-1614-0648288

US3232048
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:04:06
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'PATIENT RECEIVED PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBE'	Jerrica Sullivan (b) (4) (b) (4)	19 Jan 2021 13:52:34

FDA-CBER-2022-1614-0648289

US3232048
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:04:06
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Adverse Event (AE)'	Jerrica Sullivan (b) (4) (b) (4)	19 Jan 2021 13:52:34

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US3232048
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:04:06
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	19 Jan 2021 13:52:34

FDA-CBER-2022-1614-0648291

US3232048
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:04:06
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 08:04:03
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User closed query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	25 Jan 2021 21:26:25
User entered '12 Dec 2020' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 21:26:25
User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	25 Jan 2021 21:26:01
User entered '12 Jan 2021'	Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 21:26:01

US3232048
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:04:06
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 08:04:03
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Death (DEATH)'	Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 21:26:01

US3232048

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:04:06

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) (b) (4), (b) (6)	27 Apr 2021 08:04:03
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered empty.	Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 21:26:01

US3232048
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:04:06
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 08:04:03
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	23 Apr 2021 15:21:01
User closed query 'Per CDM: Per CCGs and entry of an AE with death as the outcome, Cause of death needs to be updated to "Adverse Event". Please confirm and amend.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 11:19:30
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	19 Apr 2021 12:58:08
Query 'Per CDM: Per CCGs and entry of an AE with death as the outcome, Cause of death needs to be updated to "Adverse Event". Please confirm and amend.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	19 Apr 2021 12:57:52
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	19 Apr 2021 12:57:36
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	19 Apr 2021 12:57:36
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Apr 2021 12:57:36
User opened query 'Per CDM: Per CCGs and entry of an AE with death as the outcome, Cause of death needs to be updated to "Adverse Event". Please confirm and amend.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Apr 2021 16:28:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'Other (OTHER)'	Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 21:26:01

US3232048
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:04:06
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 08:04:03
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	23 Apr 2021 15:21:01
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	19 Apr 2021 12:58:08
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	19 Apr 2021 12:58:08
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'complications OF ALS' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 18:00:30
User entered 'continuation of ALS'	Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 21:26:01

US3232048
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:04:06
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 08:04:03
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '12 Dec 2020'	Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 21:26:01

US3232048
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:04:06
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 08:04:03
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered 'No (N)'	Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 21:26:01

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'USA-US105-2020-MRNA-1273-P301000003'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648299

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648300

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:37:20
Un-reviewed for Safety.	System	22 Dec 2020 16:01:12
User entered 'Yes (Y)'	System	22 Dec 2020 16:01:12
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648304

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648305

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rambod'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rouhbakhsh'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648308

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MediSync Clinical Research Hattiesburg Clinic'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Petal'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MS'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered '39465'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Dec 2020 13:56:44
User entered 'US'	System	11 Dec 2020 15:25:07

FDA-CBER-2022-1614-0648313

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '5'	System	12 Mar 2021 17:11:48
User entered '4'	System	22 Dec 2020 20:37:44
User entered '3'	System	17 Dec 2020 19:10:25
User entered '2'	System	14 Dec 2020 13:56:56
User entered '1'	System	11 Dec 2020 15:25:07

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'USA-US105-2020-MRNA-1273-P301000003'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:37:20
Un-reviewed for Safety.	System	22 Dec 2020 16:01:12
User entered 'Yes (Y)'	System	22 Dec 2020 16:01:12
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rambod'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rouhbakhsh'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648324

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MediSync Clinical Research Hattiesburg Clinic'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648325

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Petal'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648326

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MS'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648327

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered '39465'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648328

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Dec 2020 13:56:44
User entered 'US'	System	11 Dec 2020 15:25:07

FDA-CBER-2022-1614-0648329

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '5'	System	12 Mar 2021 17:11:48
User entered '4'	System	22 Dec 2020 20:37:44
User entered '3'	System	17 Dec 2020 19:10:25
User entered '2'	System	14 Dec 2020 13:56:56
User entered '1'	System	11 Dec 2020 15:25:07

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 16:04:06
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '11/Dec/2020 10:25'	System	11 Dec 2020 15:25:07

US3232048

Folder: SAE USA-US105-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:04:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Dec 2020 13:56:44
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:25:07

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'USA-US105-2020-MRNA-1273-P301000003'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:37:20
Un-reviewed for Safety.	System	22 Dec 2020 16:01:12
User entered 'Yes (Y)'	System	22 Dec 2020 16:01:12
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648336

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648337

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648338

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648339

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rambod'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rouhbakhsh'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648342

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MediSync Clinical Research Hattiesburg Clinic'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648343

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Petal'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648344

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MS'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered '39465'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648346

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Dec 2020 13:56:44
User entered 'US'	System	11 Dec 2020 15:25:07

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '5'	System	12 Mar 2021 17:11:48
User entered '4'	System	22 Dec 2020 20:37:44
User entered '3'	System	17 Dec 2020 19:10:25
User entered '2'	System	14 Dec 2020 13:56:56
User entered '1'	System	11 Dec 2020 15:25:07

FDA-CBER-2022-1614-0648348

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 16:04:06
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '14/Dec/2020 13:56'	System	14 Dec 2020 13:56:56

US3232048

Folder: SAE USA-US105-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:04:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	17 Dec 2020 19:10:02
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	14 Dec 2020 13:56:56

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'USA-US105-2020-MRNA-1273-P301000003'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648351

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:37:20
Un-reviewed for Safety.	System	22 Dec 2020 16:01:12
User entered 'Yes (Y)'	System	22 Dec 2020 16:01:12
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648354

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648355

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648357

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648358

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rambod'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648359

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rouhbakhsh'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648360

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MediSync Clinical Research Hattiesburg Clinic'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Petal'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648362

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MS'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648363

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered '39465'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648364

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Dec 2020 13:56:44
User entered 'US'	System	11 Dec 2020 15:25:07

FDA-CBER-2022-1614-0648365

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '5'	System	12 Mar 2021 17:11:48
User entered '4'	System	22 Dec 2020 20:37:44
User entered '3'	System	17 Dec 2020 19:10:25
User entered '2'	System	14 Dec 2020 13:56:56
User entered '1'	System	11 Dec 2020 15:25:07

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 16:04:06
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '17/Dec/2020 19:10'	System	17 Dec 2020 19:10:25

US3232048

Folder: SAE USA-US105-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:04:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:37:20
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	17 Dec 2020 19:10:25

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'USA-US105-2020-MRNA-1273-P301000003'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648369

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:37:20
Un-reviewed for Safety.	System	22 Dec 2020 16:01:12
User entered 'Yes (Y)'	System	22 Dec 2020 16:01:12
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648374

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648376

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rambod'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648377

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rouhbakhsh'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648378

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MediSync Clinical Research Hattiesburg Clinic'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Petal'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648380

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MS'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648381

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered '39465'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648382

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Dec 2020 13:56:44
User entered 'US'	System	11 Dec 2020 15:25:07

FDA-CBER-2022-1614-0648383

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '5'	System	12 Mar 2021 17:11:48
User entered '4'	System	22 Dec 2020 20:37:44
User entered '3'	System	17 Dec 2020 19:10:25
User entered '2'	System	14 Dec 2020 13:56:56
User entered '1'	System	11 Dec 2020 15:25:07

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 16:04:06
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
User entered '22/Dec/2020 15:37'	System	22 Dec 2020 20:37:44

US3232048

Folder: SAE USA-US105-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:04:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:37:56
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:37:44

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'USA-US105-2020-MRNA-1273-P301000003'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648387

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 20:37:20
Un-reviewed for Safety.	System	22 Dec 2020 16:01:12
User entered 'Yes (Y)'	System	22 Dec 2020 16:01:12
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648390

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648391

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Yes (Y)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648392

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'No (N)'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648394

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rambod'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648395

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Rouhbakhsh'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648396

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MediSync Clinical Research Hattiesburg Clinic'	System	11 Dec 2020 15:20:16

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'Petal'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648398

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered 'MS'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648399

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Dec 2020 15:23:59
User entered '39465'	System	11 Dec 2020 15:20:16

FDA-CBER-2022-1614-0648400

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	05 Mar 2021 19:05:48
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Dec 2020 13:56:44
User entered 'US'	System	11 Dec 2020 15:25:07

FDA-CBER-2022-1614-0648401

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:04:06
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User entered '5'	System	12 Mar 2021 17:11:48
User entered '4'	System	22 Dec 2020 20:37:44
User entered '3'	System	17 Dec 2020 19:10:25
User entered '2'	System	14 Dec 2020 13:56:56
User entered '1'	System	11 Dec 2020 15:25:07

FDA-CBER-2022-1614-0648402

US3232048
Folder: SAE USA-US105-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 16:04:06
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:49:53
User entered '12/Mar/2021 12:11'	System	12 Mar 2021 17:11:48

FDA-CBER-2022-1614-0648403

US3232048

Folder: SAE USA-US105-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:04:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:47:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	12 Mar 2021 19:49:53
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 17:11:48