US3012073 (Prod: Benchmark Research-Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:52:36

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US3012073
Form: Participant Creation
Data signed: (b) (4) **12 Mar 2021 19:15:22**
Generated On: 09 Jun 2021 14:52:36

Participant ID	US3012073

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0000002

US3012073
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0000003

US3012073
Folder: Screening
Form: Demographics
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female ☐ Male ■
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	EURO AMERICAN
Unknown	False
Not reported	False

US3012073
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

Date of Informed Consent *(dd MMM yyyy)*	06 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-2022-1614-0000005

US3012073
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000006

US3012073
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0000007

US3012073
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

Condition	SEASONAL ALLERGIES, UNSPECIFIED
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0000008

US3012073
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

Condition	LOW TESTERONE
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3012073
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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

US3012073
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

Condition	DIFFICULTY SWALLOWING
Start date (dd MMM yyyy)	28 JUN 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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3012073
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

Condition	LOSS OF CONTROL OF TONGUE MUSCLES
Start date (dd MMM yyyy)	28 JUN 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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0000012

US3012073
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	06 AUG 2020
Time of assessment *(00:00-23:59)*	16:59 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:59
Height *(xxx.x)*	67.0 in
Weight *(xxx.x)*	141.3 lb
BMI *(xxx.x)*	22.17698 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012073
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	06 AUG 2020

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

US3012073
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

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	PERSONAL SECURITY

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

US3012073
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **12 Feb 2021 20:08:01**
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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)	True
Other	False
Specify	

FDA-CBER-2022-1614-0000016

US3012073
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0000017

US3012073
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

What was the date of randomization? *(dd MMM yyyy)*	06 AUG 2020
What was the participant's randomization number?	184996
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 ■

FDA-CBER-2022-1614-0000018

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0000019

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

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)*	06 AUG 2020
Time of assessment *(00:00-23:59)*	16:59 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:59
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	74 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	68 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0000020

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

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)*	06 AUG 2020
Time of assessment *(00:00-23:59)*	20:12 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 20:12
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

US3012073
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

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-2022-1614-0000022

US3012073
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

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)*	06 AUG 2020
What was the treatment time? *(00:00-23:59)*	19:37 (24 HR)
Treatment Date and Time (derived)	06 AUG 2020 19:37
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-2022-1614-0000023

US3012073
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	06 AUG 2020
Collection time *(00:00-23:59)*	18:50 (24 HR)
Collection date and time (derived)	06 AUG 2020 18:50

FDA-CBER-2022-1614-0000024

US3012073
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Collection date *(dd MMM yyyy)*			06 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	19:00	06 AUG 2020 19:00
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0000025

US3012073
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000026

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 AUG 2020 20:12
PC Open Date & Time	06 AUG 2020 19:57
PC Close Date & Time	06 AUG 2020 22:27

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**	_____
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	_____
To **PREVENT** pain or fever from occurring	_____
PC Time Stamp	_____
PC Open Date & Time	06 AUG 2020 23:22
PC Close Date & Time	07 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36

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**	97.0 °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	07 AUG 2020 20:09
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36

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**	96.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 AUG 2020 04:43
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36

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**	97.5 °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	09 AUG 2020 21:12
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36

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**	97.2 °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	10 AUG 2020 19:45
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36

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

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36

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**	97.0 °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	12 AUG 2020 22:17
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36

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	06 AUG 2020 20:14
PC Open Date & Time	06 AUG 2020 19:57
PC Close Date & Time	06 AUG 2020 22:27

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	06 AUG 2020 23:22
PC Close Date & Time	07 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36

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	07 AUG 2020 20:11
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36

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	09 AUG 2020 04:45
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36

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	09 AUG 2020 21:18
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36

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	10 AUG 2020 19:45
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	_____
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	_____
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	_____
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36

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	12 AUG 2020 22:18
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0000042

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 ☐

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	06 AUG 2020 20:15
PC Open Date & Time	06 AUG 2020 19:57
PC Close Date & Time	06 AUG 2020 22:27

FDA-CBER-2022-1614-0000044

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 ☐

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	06 AUG 2020 23:22
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-0000046

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36

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 ■

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36

	Yes ☐
PC Time stamp	07 AUG 2020 20:12
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-0000048

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000049

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36

	Yes
PC Time stamp	09 AUG 2020 04:49
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36

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 ■

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36

	Yes
PC Time stamp	09 AUG 2020 21:19
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

FDA-CBER-2022-1614-0000052

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000053

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36

	Yes
PC Time stamp	10 AUG 2020 19:46
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-0000054

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36

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-2022-1614-0000055

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000056

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36

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 ■

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36

	Yes ☐
PC Time stamp	12 AUG 2020 22:18
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3012073
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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

US3012073
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000060

US3012073
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3012073
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000062

US3012073
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000063

US3012073
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000064

US3012073
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0000065

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	03 SEP 2020
Time of assessment *(00:00-23:59)*	14:56 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 14:56
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0000066

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	03 SEP 2020
Time of assessment *(00:00-23:59)*	17:07 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 17:07
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0000067

US3012073
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	03 SEP 2020

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

FDA-CBER-2022-1614-0000068

US3012073
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

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)*	3 SEP 2020
What was the treatment time? *(00:00-23:59)*	16:29 (24 HR)
Treatment Date and Time (derived)	3 SEP 2020 16:29
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

US3012073
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	03 SEP 2020
Collection time *(00:00-23:59)*	15:07 (24 HR)
Collection date and time (derived)	03 SEP 2020 15:07

FDA-CBER-2022-1614-0000070

US3012073
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

Collection date *(dd MMM yyyy)*			03 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:42	03 SEP 2020 15:42
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0000071

US3012073
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:08:01**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000072

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	03 SEP 2020 17:02
PC Open Date & Time	03 SEP 2020 16:49
PC Close Date & Time	03 SEP 2020 19:19

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**	97.0 °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	03 SEP 2020 20:14
PC Open Date & Time	03 SEP 2020 20:14
PC Close Date & Time	04 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36

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**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	04 SEP 2020 21:20
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36

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**	97.7 °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	05 SEP 2020 19:39
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	_____
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	_____
To **PREVENT** pain or fever from occurring	_____
PC Time Stamp	_____
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36

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**	96.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	07 SEP 2020 21:16
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36

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**	97.2 °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	08 SEP 2020 22:20
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 SEP 2020 23:18
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36

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	03 SEP 2020 17:03
PC Open Date & Time	03 SEP 2020 16:49
PC Close Date & Time	03 SEP 2020 19:19

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36

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	03 SEP 2020 20:15
PC Open Date & Time	03 SEP 2020 20:14
PC Close Date & Time	04 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36

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	04 SEP 2020 21:20
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36

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	05 SEP 2020 19:39
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	_____
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	_____
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	_____
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36

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	07 SEP 2020 21:17
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36

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	08 SEP 2020 22:20
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36

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	09 SEP 2020 23:19
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

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

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	03 SEP 2020 17:03
PC Open Date & Time	03 SEP 2020 16:49
PC Close Date & Time	03 SEP 2020 19:19

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000091

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	03 SEP 2020 20:16
PC Open Date & Time	03 SEP 2020 20:14
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-0000092

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000093

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36

	Yes
PC Time stamp	04 SEP 2020 21:21
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-0000094

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000095

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36

	Yes ☐
PC Time stamp	05 SEP 2020 19:40
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36

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 ☐

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36

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

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36

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 ■

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36

	Yes
PC Time stamp	07 SEP 2020 21:17
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-0000100

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36

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 ■

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36

	Yes
PC Time stamp	08 SEP 2020 22:20
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36

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 ■

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36

	Yes
PC Time stamp	09 SEP 2020 23:19
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3012073
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3012073
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000106

US3012073
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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

US3012073
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000108

US3012073
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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*	

US3012073
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:08:00**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000110

US3012073
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 20:08:02**
Generated On: 09 Jun 2021 14:52:36

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-0000111

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 20:08:02**
Generated On: 09 Jun 2021 14:52:36

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	1 OCT 2020
Time of assessment *(00:00-23:59)*	10:55 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:55
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012073
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 20:08:02**
Generated On: 09 Jun 2021 14:52:36

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.

US3012073
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 20:08:02**
Generated On: 09 Jun 2021 14:52:36

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	1 OCT 2020
Collection time *(00:00-23:59)*	11:03 (24 HR)
Collection date and time (derived)	1 OCT 2020 11:03

US3012073
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:08:02**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000115

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

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	08 OCT 2020 21:40:34
Patient Cloud Open Date & Time	06 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

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	13 OCT 2020 00:14:09
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

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	21 OCT 2020 11:14:00
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

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	06 NOV 2020 18:39:20
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

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	14 NOV 2020 11:57:25
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

FDA-CBER-2022-1614-0000120

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 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 ☐

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 07:31:35
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 14:16:25
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please 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 ☐

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

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

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 09:32:58
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 11:49:00
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 10:50:54
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 10:55:04
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 10:38:36
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 10:51:58
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 18:24:23
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 16:09:38
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 11:12:15
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 194
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	13 FEB 2021 19:24:04
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 201
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	20 FEB 2021 00:02:02
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36

TIMEPOINT	DAY 208
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 FEB 2021 14:06:48
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3012073

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:52:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 14:07:21

US3012073
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:23:28**
Generated On: 09 Jun 2021 14:52:36

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3012073
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:23:28**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000141

US3012073
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

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

US3012073
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000143

US3012073
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3012073
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000145

US3012073
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	02 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3012073
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000147

US3012073
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36

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-2022-1614-0000148

US3012073
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36

Were vital signs assessed?	Yes ☐ No ☐
Date of assessment *(dd MMM yyyy)*	
Time of assessment *(00:00-23:59)*	
Vital Signs Date and Time (derived)	
Temperature *(xxx.x)*	
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	
Pulse units	
Respiratory Rate *(xxx)*	
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	
Systolic Blood Pressure units	
Diastolic Blood Pressure *(xxx)*	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0000149

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.

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

US3012073
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000152

US3012073
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 14:52:36

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-2022-1614-0000153

US3012073
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 14:52:36

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-0000154

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	11 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-0000155

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **09 Apr 2021 20:38:23**
Generated On: 09 Jun 2021 14:52:36

Date of updated informed consent *(dd MMM yyyy)*	11 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ■
Date of unblinding *(dd MMM yyyy)*	11 JAN 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ■
Actual Dose 1	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Will participant receive mRNA-1273?	Yes ■ No ☐
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Height	66.5 in
Weight	131.8 lb
BMI (xxx.x)	20.99820

FDA-CBER-2022-1614-0000157

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Height	66.5 in
Weight	131.8 lb
BMI (xxx.x)	20.99820
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	11 JAN 2021
Time of assessment *(00:00-23:59)*	15:42 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 15:42
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	92 mmHg
Diastolic Blood Pressure units	MMHG

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Height	66.5 in
Weight	131.8 lb
BMI (xxx.x)	20.99820
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	

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	11 JAN 2021

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

FDA-CBER-2022-1614-0000160

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

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? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	11 JAN 2021
What was the treatment time? *(00:00-23:59)*	17:33 (24 HR)
Treatment Date and Time (derived)	11 JAN 2021 17:33
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

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	11 JAN 2021
Collection time *(00:00-23:59)*	17:07 (24 HR)
Collection date and time (derived)	11 JAN 2021 17:07

FDA-CBER-2022-1614-0000162

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	11 JAN 2021
Collection time *(00:00 - 23:59)*	16:05
Collection Date and Time (derived)	11 JAN 2021 16:05

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000164

US3012073
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3012073
Folder: Safety Call OL-D8 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

FDA-CBER-2022-1614-0000166

US3012073
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	08 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD29

FDA-CBER-2022-1614-0000167

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	08 FEB 2021
Time of assessment *(00:00-23:59)*	16:09 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 16:09
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	89 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	08 FEB 2021
Time of assessment *(00:00-23:59)*	17:18 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 17:18
Temperature *(xxx.x)*	98.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

US3012073
Folder: OL-D29 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	08 FEB 2021

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

US3012073
Folder: OL-D29 (1)
Form: Exposure
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

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? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	08 FEB 2021
What was the treatment time? *(00:00-23:59)*	16:47 (24 HR)
Treatment Date and Time (derived)	08 FEB 2021 16:47
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

US3012073
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000172

US3012073
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3012073
Folder: Safety Call OL-D36 (1)
Form: Continuing
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

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

FDA-CBER-2022-1614-0000174

US3012073
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **26 Mar 2021 00:47:02**
Generated On: 09 Jun 2021 14:52:36

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	05 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD57

FDA-CBER-2022-1614-0000175

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Mar 2021 00:47:02**
Generated On: 09 Jun 2021 14:52:36

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	05 MAR 2021
Time of assessment *(00:00-23:59)*	16:00 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 16:00
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	112 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0000176

US3012073
Folder: OL-D57 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Mar 2021 00:47:02**
Generated On: 09 Jun 2021 14:52:36

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	05 MAR 2021

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

US3012073
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Mar 2021 00:47:02**
Generated On: 09 Jun 2021 14:52:36

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	05 MAR 2021
Collection time *(00:00-23:59)*	16:48 (24 HR)
Collection date and time (derived)	05 MAR 2021 16:48

US3012073
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **12 Mar 2021 19:15:23**
Generated On: 09 Jun 2021 14:52:36

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

If Yes, enter details on the Adverse Events form.

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **15 Apr 2021 16:35:01**
Generated On: 09 Jun 2021 14:52:36

AEID	USA-US006-2021-MRNA-1273-P30 1000006
Adverse event	WORSENING 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)*	26 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ■ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	26 FEB 2021
Hospital Discharge Date *(dd MMM yyyy)*	02 MAR 2021
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	False
Concomitant Medication	True
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	PT WAS ADMITTED TO HOSPITAL DUE TO DEHYDRATION AND MALNUTRITION, AS A RESULT OF WORSENING ALS
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **15 Apr 2021 16:35:01**
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Admitted to ICU Derived (CSA Programming Field Only)	0

FDA-CBER-2022-1614-0000182

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **12 Mar 2021 19:15:23**
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Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

FDA-CBER-2022-1614-0000183

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	TESTOSTERONE
Prophylaxis	Yes ☐ No ■
Indication	HORMONE REPLACEMENT
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ■ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ■ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ■
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	1 JAN 2015
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	1 JAN 2021
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 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ■ No ☐
Indication	INFLUENZA PREVENTION
Dose per administration	.7
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)*	29 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	29 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 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	PNEUMOCOCCAL VACCINE
Prophylaxis	Yes ■ No ☐
Indication	PNEUMONIA PREVENTION
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)*	29 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	29 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 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	GYCOPYROLATE
Prophylaxis	Yes ☐ No ■
Indication	EXCESS SALIVA, DUE TO WORSENING OF ALS
Dose per administration	UN
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNKNOWN
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)*	05 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	TRAMADOL
Prophylaxis	Yes ☐ No ■
Indication	PAIN, DUE TO WORSENING OF ALS
Dose per administration	UN
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNKNOWN
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)*	05 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ■
Indication	WORSENING OF ALS (AE #1)
Dose per administration	650
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)*	26 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	02 MAR 2021
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	DEXTROSE/WATER
Prophylaxis	Yes ☐ No ■
Indication	WORSENING OF ALS (AE #1)
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)*	26 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	02 MAR 2021
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	SODIUM CHLORIDE 0.9%
Prophylaxis	Yes No
Indication	WORSENING OF ALS (AE #1)
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	CONTINOUS
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)*	26 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	26 FEB 2021
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	MAALOX
Prophylaxis	Yes ☐ No ■
Indication	WORSENING OF ALS (AE #1)
Dose per administration	30
Dose unit	mg ☐ ug ☐ mL ■ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
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)*	26 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	02 MAR 2021
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
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Name of Medication	DOCUSATE SODIUM
Prophylaxis	Yes ☐ No ■
Indication	WORSENING OF ALS (AE #1)
Dose per administration	100
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	26 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	02 MAR 2021
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 ■

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	MAGNESIUM HYDROXIDE
Prophylaxis	Yes ☐ No ■
Indication	WORSENING OF ALS (AE #1)
Dose per administration	30
Dose unit	mg ☐ ug ☐ mL ■ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	Q6H
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)*	26 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	02 MAR 2021
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	ONDASETRON
Prophylaxis	Yes ☐ No ■
Indication	WORSENING OF ALS (AE #1)
Dose per administration	4
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ 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)*	26 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	02 MAR 2021
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	GUAIFENESIN/DEXTROMETHORPHAN
Prophylaxis	Yes No
Indication	WORSENING OF ALS (AE #1)
Dose per administration	10
Dose unit	mg ug mL g IU tablet capsule puff Other
If dose unit is Other, specify	
Frequency	once daily twice daily three times daily four times daily every other day every week every month as needed once unknown other
If frequency is Other, specify	Q4H
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)*	26 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	02 MAR 2021
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **16 Apr 2021 22:33:21**
Generated On: 09 Jun 2021 14:52:36

Name of Medication	MELATONIN
Prophylaxis	Yes ☐ No ■
Indication	WORSENING OF ALS (AE #1)
Dose per administration	6
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	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)*	26 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	02 MAR 2021
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 ■

US3012073
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **16 Apr 2021 18:17:24**
Generated On: 09 Jun 2021 14:52:36

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

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US3012073
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **15 Apr 2021 21:32:08**
Generated On: 09 Jun 2021 14:52:36

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
26 FEB 2021	FEEDING TUBE	Adverse Event	

FDA-CBER-2022-1614-0000213

US3012073
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **08 Apr 2021 14:49:05**
Generated On: 09 Jun 2021 14:52:36

Date of study discontinuation/completion *(dd MMM yyyy)*	05 MAR 2021
Reason for discontinuation	AE (specify) ☐ SAE (specify) ■ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	#1
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

FDA-CBER-2022-1614-0000214

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:52:36

SAEID	USA-US006-2021-MRNA-1273-P301000006
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form (1)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:52:36

SAEID	USA-US006-2021-MRNA-1273-P301000006
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:28
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

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form (2)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:52:36

SAEID	USA-US006-2021-MRNA-1273-P301000006
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	15/APR/2021 10:05
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

US3012073 (Prod: Benchmark Research-Austin)

US3012073
Form: Participant Creation
Generated On: 09 Jun 2021 14:52:36
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:11:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'US3012073'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 21:54:16

FDA-CBER-2022-1614-0000219

US3012073
Form: Participant Creation
Generated On: 09 Jun 2021 14:52:36

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0000220

US3012073
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:33:01

US3012073
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 21:54:17

FDA-CBER-2022-1614-0000222

US3012073
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:33:01

FDA-CBER-2022-1614-0000223

US3012073
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'SCRN'	System	07 Aug 2020 00:33:01

FDA-CBER-2022-1614-0000224

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 21:54:18

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '70'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'YEARS'	System	07 Aug 2020 00:42:35

FDA-CBER-2022-1614-0000227

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '70'	System	07 Aug 2020 01:10:32

FDA-CBER-2022-1614-0000228

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Male (M)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 14:51:43
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

FDA-CBER-2022-1614-0000231

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

FDA-CBER-2022-1614-0000232

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

FDA-CBER-2022-1614-0000233

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '1' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 14:51:43
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

FDA-CBER-2022-1614-0000236

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Euro American' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 14:51:43
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

FDA-CBER-2022-1614-0000237

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

FDA-CBER-2022-1614-0000238

US3012073
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:52:36
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 00:42:35

FDA-CBER-2022-1614-0000239

US3012073
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:52:36
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '06 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:10:32

FDA-CBER-2022-1614-0000240

US3012073
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:52:36
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'Aug 2020'	System	07 Aug 2020 01:10:32

FDA-CBER-2022-1614-0000241

US3012073
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:52:36
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '2020'	System	07 Aug 2020 01:10:32

FDA-CBER-2022-1614-0000242

US3012073
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:52:36
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Amendment 1 (1)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:10:32

FDA-CBER-2022-1614-0000243

US3012073
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:52:36
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:10:32

US3012073
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:52:36
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:10:32

US3012073
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:52:36
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:10:32

US3012073
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:52:36
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:10:32

FDA-CBER-2022-1614-0000247

US3012073
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:52:36
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 21:54:17

FDA-CBER-2022-1614-0000248

US3012073
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:52:36
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '1'	System	07 Aug 2020 01:10:32

FDA-CBER-2022-1614-0000249

US3012073
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 14:52:36
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:10:21

FDA-CBER-2022-1614-0000250

US3012073
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 14:52:36
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:28:20

US3012073
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:52:36
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 01:30:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 01:30:09
Data point term sent to Coder	System	07 Aug 2020 01:29:28
User entered 'seasonal allergies, unspecified'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:28:35

FDA-CBER-2022-1614-0000252

US3012073
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:52:36
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'UN UNK 1980'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:28:35

FDA-CBER-2022-1614-0000253

US3012073
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:28:35

FDA-CBER-2022-1614-0000254

US3012073
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:52:36
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:28:35

FDA-CBER-2022-1614-0000255

US3012073
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:52:36
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:28:35

FDA-CBER-2022-1614-0000256

US3012073
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:52:36
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:28:35

FDA-CBER-2022-1614-0000257

US3012073
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:52:36
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'Jan 1980'	System	07 Aug 2020 01:28:35

FDA-CBER-2022-1614-0000258

US3012073
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:52:36
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '1980'	System	07 Aug 2020 01:28:35

FDA-CBER-2022-1614-0000259

US3012073
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:52:36
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered empty.	System	07 Aug 2020 01:28:35

FDA-CBER-2022-1614-0000260

US3012073
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:52:36
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered empty.	System	07 Aug 2020 01:28:35

FDA-CBER-2022-1614-0000261

US3012073
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:52:36
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 11:34:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 11:34:09
Data point term sent to Coder	System	07 Aug 2020 01:29:28
User entered 'low testerone'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:11

US3012073
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:52:36
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'UN UNK 2014'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:11

FDA-CBER-2022-1614-0000263

US3012073
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:11

FDA-CBER-2022-1614-0000264

US3012073
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:52:36
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:11

FDA-CBER-2022-1614-0000265

US3012073
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:52:36
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:11

FDA-CBER-2022-1614-0000266

US3012073
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:52:36
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:11

FDA-CBER-2022-1614-0000267

US3012073
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:52:36
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'Jan 2014'	System	07 Aug 2020 01:29:11

FDA-CBER-2022-1614-0000268

US3012073
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:52:36
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '2014'	System	07 Aug 2020 01:29:11

FDA-CBER-2022-1614-0000269

US3012073
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:52:36
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered empty.	System	07 Aug 2020 01:29:11

FDA-CBER-2022-1614-0000270

US3012073
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:52:36
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered empty.	System	07 Aug 2020 01:29:11

FDA-CBER-2022-1614-0000271

US3012073
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:52:36
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 01:32:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 01:32:13
Data point term sent to Coder	System	07 Aug 2020 01:30:29
User entered 'prostate cancer'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:29

FDA-CBER-2022-1614-0000272

US3012073
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:52:36
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'UN Nov 2015'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:29

FDA-CBER-2022-1614-0000273

US3012073
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:29

FDA-CBER-2022-1614-0000274

US3012073
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:52:36
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:29

FDA-CBER-2022-1614-0000275

US3012073
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:52:36
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'UN Nov 2015'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:29

US3012073
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:52:36
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:29:29

FDA-CBER-2022-1614-0000277

US3012073
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:52:36
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'Nov 2015'	System	07 Aug 2020 01:29:29

FDA-CBER-2022-1614-0000278

US3012073
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:52:36
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '2015'	System	07 Aug 2020 01:29:29

US3012073
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:52:36
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'Nov 2015'	System	07 Aug 2020 01:29:29

FDA-CBER-2022-1614-0000280

US3012073
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:52:36
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '2015'	System	07 Aug 2020 01:29:29

FDA-CBER-2022-1614-0000281

US3012073
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:52:36
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Dysphagia, LLT: Swallowing difficult - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:54:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:54:34
Data point term sent to Coder	System	11 Nov 2020 14:53:59
User entered 'Difficulty Swallowing'	Pamela Fidler (b) (4)	11 Nov 2020 14:53:15

FDA-CBER-2022-1614-0000282

US3012073
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:52:36
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '28 Jun 2020'	Pamela Fidler (b) (4)	11 Nov 2020 14:53:15

FDA-CBER-2022-1614-0000283

US3012073
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Pamela Fidler (b) (4)	11 Nov 2020 14:53:15

FDA-CBER-2022-1614-0000284

US3012073
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:52:36
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	11 Nov 2020 14:53:15

FDA-CBER-2022-1614-0000285

US3012073
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:52:36
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Pamela Fidler (b) (4)	11 Nov 2020 14:53:15

FDA-CBER-2022-1614-0000286

US3012073
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:52:36
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Pamela Fidler (b) (4)	11 Nov 2020 14:53:15

FDA-CBER-2022-1614-0000287

US3012073
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:52:36
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'Jun 2020'	System	11 Nov 2020 14:53:15

FDA-CBER-2022-1614-0000288

US3012073
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:52:36
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '2020'	System	11 Nov 2020 14:53:15

FDA-CBER-2022-1614-0000289

US3012073
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:52:36
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered empty.	System	11 Nov 2020 14:53:15

FDA-CBER-2022-1614-0000290

US3012073
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:52:36
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered empty.	System	11 Nov 2020 14:53:15

FDA-CBER-2022-1614-0000291

US3012073
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:52:36
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Tongue conditions, HLT: Tongue signs and symptoms, PT: Tongue movement disturbance, LLT: Tongue movement disturbance - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 11:46:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 11:46:41
Data point term sent to Coder	System	11 Nov 2020 14:53:59
User entered 'Loss of control of Tongue muscles'	Pamela Fidler (b) (4)	11 Nov 2020 14:53:53

US3012073
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:52:36
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '28 Jun 2020'	Pamela Fidler (b) (4)	11 Nov 2020 14:53:53

FDA-CBER-2022-1614-0000293

US3012073
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Pamela Fidler (b) (4)	11 Nov 2020 14:53:53

FDA-CBER-2022-1614-0000294

US3012073
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:52:36
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	11 Nov 2020 14:53:53

FDA-CBER-2022-1614-0000295

US3012073
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:52:36
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Pamela Fidler (b) (4)	11 Nov 2020 14:53:53

FDA-CBER-2022-1614-0000296

US3012073
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:52:36
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Pamela Fidler (b) (4)	11 Nov 2020 14:53:53

FDA-CBER-2022-1614-0000297

US3012073
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:52:36
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'Jun 2020'	System	11 Nov 2020 14:53:53

FDA-CBER-2022-1614-0000298

US3012073
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:52:36
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '2020'	System	11 Nov 2020 14:53:53

FDA-CBER-2022-1614-0000299

US3012073
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:52:36
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered empty.	System	11 Nov 2020 14:53:53

FDA-CBER-2022-1614-0000300

US3012073
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:52:36
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered empty.	System	11 Nov 2020 14:53:53

FDA-CBER-2022-1614-0000301

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00

FDA-CBER-2022-1614-0000302

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '06 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '16:59'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '06 Aug 2020 16:59'	System	07 Aug 2020 01:22:00

FDA-CBER-2022-1614-0000305

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '67.0' in	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00
DataPoint set to visible.	System	07 Aug 2020 01:10:32

FDA-CBER-2022-1614-0000306

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '141.3' lb	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00
DataPoint set to visible.	System	07 Aug 2020 01:10:32

FDA-CBER-2022-1614-0000307

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
Amendment Manager: User entered '22.17698'	System	16 Sep 2020 23:46:37
User entered '22.2'	System	07 Aug 2020 01:22:00
DataPoint set to visible.	System	07 Aug 2020 01:10:32

FDA-CBER-2022-1614-0000308

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'kg/m2'	System	07 Aug 2020 01:22:00
DataPoint set to visible.	System	07 Aug 2020 01:10:32

FDA-CBER-2022-1614-0000309

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:17:24
User entered '98.5' F	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:17:24
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00

FDA-CBER-2022-1614-0000312

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 23:17:31
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 23:17:31
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:17:31
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 23:17:24
User entered empty; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:17:24
User entered '74'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'bpm'	System	03 Sep 2020 23:17:31
User entered empty.	System	03 Sep 2020 23:17:24
User entered 'bpm'	System	07 Aug 2020 01:22:00

FDA-CBER-2022-1614-0000314

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 23:17:31
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 23:17:31
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:17:31
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 23:17:24
User entered empty; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:17:24
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'breaths/min'	System	03 Sep 2020 23:17:31
User entered empty.	System	03 Sep 2020 23:17:24
User entered 'breaths/min'	System	07 Aug 2020 01:22:00

FDA-CBER-2022-1614-0000316

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 23:17:31
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 23:17:31
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:17:31
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 23:17:24
User entered empty; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:17:24
User entered '124'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	03 Sep 2020 23:17:31
User entered empty.	System	03 Sep 2020 23:17:24
User entered 'mmHg'	System	07 Aug 2020 01:22:00

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US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 23:17:31
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	03 Sep 2020 23:17:31
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:17:31
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 23:17:24
User entered empty; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:17:24
User entered '68'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:00

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	03 Sep 2020 23:17:31
User entered empty.	System	03 Sep 2020 23:17:24
User entered 'mmHg'	System	07 Aug 2020 01:22:00

FDA-CBER-2022-1614-0000320

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05

FDA-CBER-2022-1614-0000321

US3012073
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05

FDA-CBER-2022-1614-0000322

US3012073
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:10

FDA-CBER-2022-1614-0000323

US3012073
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 12:05:21
Comment added '06 Aug 2020 = 06 Aug 2020".	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:18:35
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 21:27:58
User entered '06 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:22:10

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

FDA-CBER-2022-1614-0000328

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

FDA-CBER-2022-1614-0000331

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

FDA-CBER-2022-1614-0000332

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

FDA-CBER-2022-1614-0000333

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

FDA-CBER-2022-1614-0000334

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

FDA-CBER-2022-1614-0000336

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Personal Security'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

FDA-CBER-2022-1614-0000337

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 14:55:05
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

FDA-CBER-2022-1614-0000338

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

US3012073

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:36

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '1' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 14:55:05
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

FDA-CBER-2022-1614-0000343

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

FDA-CBER-2022-1614-0000344

US3012073
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:52:36
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:28

US3012073
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:39

FDA-CBER-2022-1614-0000346

US3012073
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '06 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:39

US3012073
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:23:39

FDA-CBER-2022-1614-0000348

US3012073
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'VISIT1'	System	07 Aug 2020 01:23:39

FDA-CBER-2022-1614-0000349

US3012073
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:52:36
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 00:14:12

FDA-CBER-2022-1614-0000350

US3012073
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:52:36
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:43:57
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:43:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 00:14:12
User entered '184996' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 00:14:12

FDA-CBER-2022-1614-0000351

US3012073
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:52:36
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 00:14:12

FDA-CBER-2022-1614-0000352

US3012073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:36

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:03

US3012073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:36

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:03

US3012073
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:52:36
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:03

FDA-CBER-2022-1614-0000355

US3012073
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:52:36
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:03

FDA-CBER-2022-1614-0000356

US3012073
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:52:36
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:03

FDA-CBER-2022-1614-0000357

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:18:04
User entered '67.0' in	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:18:04
User entered '141.3' lb	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:18:04
User entered '67.0' in	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:18:04
User entered '141.3' lb	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000362

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000363

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '06 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000364

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '16:59'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000365

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '06 Aug 2020 16:59'	System	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000366

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 01:25:05
User entered '98.5' F reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 01:24:59
User entered '98.5' (non-conformant).	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000367

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000368

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000369

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '74'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000370

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'bpm'	System	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000371

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000372

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'breaths/min'	System	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000373

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '124'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000374

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000375

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '68'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000376

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	07 Aug 2020 01:24:59

FDA-CBER-2022-1614-0000377

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:18:04
User entered '67.0' in	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:18:04
User entered '141.3' lb	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:24:59

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000380

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 01:26:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 01:26:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:03
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 01:25:05
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000381

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '06 Aug 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 10:56:49
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, post-dose observation is 30 minutes, not 60' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:25
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	07 Aug 2020 01:26:03
User entered '20:12' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000383

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '06 Aug 2020 20:12'	System	07 Aug 2020 01:26:03
User entered empty.	System	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000384

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '98.3' F reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000387

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '64' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000388

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'bpm'	System	07 Aug 2020 01:26:03
User entered empty.	System	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000389

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '14' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000390

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'breaths/min'	System	07 Aug 2020 01:26:03
User entered empty.	System	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000391

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '154' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000392

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	07 Aug 2020 01:26:03
User entered empty.	System	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000393

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '70' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:25:05

FDA-CBER-2022-1614-0000394

US3012073
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	07 Aug 2020 01:26:03
User entered empty.	System	07 Aug 2020 01:25:05

US3012073
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)' reason for change: Data Entry Error	Lamar Box (b) (4) (b) (4)	13 Oct 2020 18:10:01
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:37

US3012073
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty; reason for change Data Entry Error	Lamar Box (b) (4) (b) (4)	13 Oct 2020 18:10:01
User entered '06 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:37

US3012073
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000398

US3012073
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:11:01

US3012073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:11:01

US3012073
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000401

US3012073
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '06 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:11:01

US3012073
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '19:37'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000403

US3012073
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '06 Aug 2020 19:37'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000404

US3012073
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000405

US3012073
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'ONCE'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000406

US3012073
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000407

US3012073
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:19:56

FDA-CBER-2022-1614-0000408

US3012073
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '06 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:19:56

FDA-CBER-2022-1614-0000409

US3012073
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '18:50'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:19:56

FDA-CBER-2022-1614-0000410

US3012073
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '06 Aug 2020 18:50'	System	07 Aug 2020 01:19:56

FDA-CBER-2022-1614-0000411

US3012073
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 14:52:36
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '06 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:20:12

US3012073
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:52:36
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:20:12

FDA-CBER-2022-1614-0000413

US3012073
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:52:36
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:20:12

US3012073
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:52:36
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '19:00'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:20:12

US3012073
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:52:36
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '06 Aug 2020 19:00'	System	07 Aug 2020 01:20:12

FDA-CBER-2022-1614-0000416

US3012073
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:52:36
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:20:12

FDA-CBER-2022-1614-0000417

US3012073
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:52:36
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:20:12

FDA-CBER-2022-1614-0000418

US3012073
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:52:36
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:20:12

US3012073
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:52:36
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered empty.	System	07 Aug 2020 01:20:12

FDA-CBER-2022-1614-0000420

US3012073
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:20:15

FDA-CBER-2022-1614-0000421

US3012073
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '1'	System	07 Aug 2020 01:20:15

FDA-CBER-2022-1614-0000422

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000423

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:12:27', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'a2052ebb-6fd1-4552-b974-dc03fda0accd'	System	07 Aug 2020 01:13:00
User entered 'Yes (Y)'	System	07 Aug 2020 01:13:00

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:12:40', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'a2052ebb-6fd1-4552-b974-dc03fda0accd'	System	07 Aug 2020 01:13:00
User entered '98.3'	System	07 Aug 2020 01:13:00

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:12:49', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'a2052ebb-6fd1-4552-b974-dc03fda0accd'	System	07 Aug 2020 01:13:00
User entered 'No (N)'	System	07 Aug 2020 01:13:00

FDA-CBER-2022-1614-0000426

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:12:57', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'a2052ebb-6fd1-4552-b974-dc03fda0accd'	System	07 Aug 2020 01:13:00
User entered '06 Aug 2020 20:12'	System	07 Aug 2020 01:13:00

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Aug 2020 19:57'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000428

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Aug 2020 22:27'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000429

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000430

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000431

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000432

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000433

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000434

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000435

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000436

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Aug 2020 23:22'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000437

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000438

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 2'	System	07 Aug 2020 01:11:01

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:07:05', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9207f77c-9ddb-40de-841c-313964f9eff9'	System	08 Aug 2020 01:09:55
User entered 'Yes (Y)'	System	08 Aug 2020 01:09:55

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:09:34', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9207f77c-9ddb-40de-841c-313964f9eff9'	System	08 Aug 2020 01:09:55
User entered '97.0'	System	08 Aug 2020 01:09:55

FDA-CBER-2022-1614-0000441

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:09:43', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9207f77c-9ddb-40de-841c-313964f9eff9'	System	08 Aug 2020 01:09:55
User entered 'No (N)'	System	08 Aug 2020 01:09:55

FDA-CBER-2022-1614-0000442

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:09:52', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9207f77c-9ddb-40de-841c-313964f9eff9'	System	08 Aug 2020 01:09:55
User entered '07 Aug 2020 20:09'	System	08 Aug 2020 01:09:55

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000444

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 3'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000446

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:42:46', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cefd24de-6775-4344-a0b5-e4173dd3374a'	System	09 Aug 2020 09:43:10
User entered 'Yes (Y)'	System	09 Aug 2020 09:43:10

FDA-CBER-2022-1614-0000447

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:42:56', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cefd24de-6775-4344-a0b5-e4173dd3374a'	System	09 Aug 2020 09:43:10
User entered '96.4'	System	09 Aug 2020 09:43:10

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:43:01', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cefd24de-6775-4344-a0b5-e4173dd3374a'	System	09 Aug 2020 09:43:10
User entered 'No (N)'	System	09 Aug 2020 09:43:10

FDA-CBER-2022-1614-0000449

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:43:07', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cefd24de-6775-4344-a0b5-e4173dd3374a'	System	09 Aug 2020 09:43:10
User entered '09 Aug 2020 04:43'	System	09 Aug 2020 09:43:10

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000451

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000452

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 4'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000453

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:11:43', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'aac61943-b3be-4e24-821e-53f023aa39b8'	System	10 Aug 2020 02:12:08
User entered 'Yes (Y)'	System	10 Aug 2020 02:12:08

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:11:51', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'aac61943-b3be-4e24-821e-53f023aa39b8'	System	10 Aug 2020 02:12:08
User entered '97.5'	System	10 Aug 2020 02:12:08

FDA-CBER-2022-1614-0000455

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:11:56', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'aac61943-b3be-4e24-821e-53f023aa39b8'	System	10 Aug 2020 02:12:08
User entered 'No (N)'	System	10 Aug 2020 02:12:08

FDA-CBER-2022-1614-0000456

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:12:06', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'aac61943-b3be-4e24-821e-53f023aa39b8'	System	10 Aug 2020 02:12:08
User entered '09 Aug 2020 21:12'	System	10 Aug 2020 02:12:08

FDA-CBER-2022-1614-0000457

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000458

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000459

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 5'	System	07 Aug 2020 01:11:01

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:44:45', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '4397cf00-fb73-4c59-9e63-b5c3cdac1d72'	System	11 Aug 2020 00:45:10
User entered 'Yes (Y)'	System	11 Aug 2020 00:45:10

FDA-CBER-2022-1614-0000461

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:44:53', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '4397cf00-fb73-4c59-9e63-b5c3cdac1d72'	System	11 Aug 2020 00:45:10
User entered '97.2'	System	11 Aug 2020 00:45:10

FDA-CBER-2022-1614-0000462

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:44:59', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '4397cf00-fb73-4c59-9e63-b5c3cdac1d72'	System	11 Aug 2020 00:45:10
User entered 'No (N)'	System	11 Aug 2020 00:45:10

FDA-CBER-2022-1614-0000463

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:45:07', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '4397cf00-fb73-4c59-9e63-b5c3cdac1d72'	System	11 Aug 2020 00:45:10
User entered '10 Aug 2020 19:45'	System	11 Aug 2020 00:45:10

FDA-CBER-2022-1614-0000464

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000465

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000466

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 6'	System	07 Aug 2020 01:11:01

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000468

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000469

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000470

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000471

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000472

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000473

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000474

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000475

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 7'	System	07 Aug 2020 01:11:01

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:17:07', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'bffb6b3a-7c54-4946-99ba-c05da411db2b'	System	13 Aug 2020 03:17:42
User entered 'Yes (Y)'	System	13 Aug 2020 03:17:42

FDA-CBER-2022-1614-0000477

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:17:26', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'bffb6b3a-7c54-4946-99ba-c05da411db2b'	System	13 Aug 2020 03:17:42
User entered '97.0'	System	13 Aug 2020 03:17:42

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:17:32', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'bffb6b3a-7c54-4946-99ba-c05da411db2b'	System	13 Aug 2020 03:17:42
User entered 'No (N)'	System	13 Aug 2020 03:17:42

FDA-CBER-2022-1614-0000479

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:17:41', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'bffb6b3a-7c54-4946-99ba-c05da411db2b'	System	13 Aug 2020 03:17:42
User entered '12 Aug 2020 22:17'	System	13 Aug 2020 03:17:42

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000481

US3012073
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000482

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 01:11:01

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:13:16', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '1838be0c-c58a-47bd-bfb7-aed5f31090c5'	System	07 Aug 2020 01:14:15
User entered 'None (1)'	System	07 Aug 2020 01:14:15

FDA-CBER-2022-1614-0000484

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:13:21', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '1838be0c-c58a-47bd-bfb7-aed5f31090c5'	System	07 Aug 2020 01:14:15
User entered 'No (N)'	System	07 Aug 2020 01:14:15

FDA-CBER-2022-1614-0000485

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:13:26', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '1838be0c-c58a-47bd-bfb7-aed5f31090c5'	System	07 Aug 2020 01:14:15
User entered 'No (N)'	System	07 Aug 2020 01:14:15

FDA-CBER-2022-1614-0000486

US3012073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:13:57', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '1838be0c-c58a-47bd-bfb7-aed5f31090c5'	System	07 Aug 2020 01:14:15
User entered 'None (1)'	System	07 Aug 2020 01:14:15

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:14:13', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '1838be0c-c58a-47bd-bfb7-aed5f31090c5'	System	07 Aug 2020 01:14:15
User entered '06 Aug 2020 20:14'	System	07 Aug 2020 01:14:15

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Aug 2020 19:57'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000489

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Aug 2020 22:27'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000490

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000491

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000492

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000493

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000494

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000495

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000496

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000497

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000498

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Aug 2020 23:22'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000499

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000500

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 2'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000501

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:10:04', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '74f35f60-074c-43aa-bd3c-a15721bbde40'	System	08 Aug 2020 01:11:35
User entered 'None (1)'	System	08 Aug 2020 01:11:35

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:10:27', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '74f35f60-074c-43aa-bd3c-a15721bbde40'	System	08 Aug 2020 01:11:35
User entered 'No (N)'	System	08 Aug 2020 01:11:35

FDA-CBER-2022-1614-0000503

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:10:31', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '74f35f60-074c-43aa-bd3c-a15721bbde40'	System	08 Aug 2020 01:11:35
User entered 'No (N)'	System	08 Aug 2020 01:11:35

US3012073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:11:11', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '74f35f60-074c-43aa-bd3c-a15721bbde40'	System	08 Aug 2020 01:11:35
User entered 'None (1)'	System	08 Aug 2020 01:11:35

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:11:30', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '74f35f60-074c-43aa-bd3c-a15721bbde40'	System	08 Aug 2020 01:11:35
User entered '07 Aug 2020 20:11'	System	08 Aug 2020 01:11:35

FDA-CBER-2022-1614-0000506

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000507

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000508

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 3'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000509

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:43:33', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '3b370d78-4344-45df-b02b-267e76190a02'	System	09 Aug 2020 09:45:04
User entered 'None (1)'	System	09 Aug 2020 09:45:04

FDA-CBER-2022-1614-0000510

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:44:03', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '3b370d78-4344-45df-b02b-267e76190a02'	System	09 Aug 2020 09:45:04
User entered 'No (N)'	System	09 Aug 2020 09:45:04

FDA-CBER-2022-1614-0000511

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:44:07', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '3b370d78-4344-45df-b02b-267e76190a02'	System	09 Aug 2020 09:45:04
User entered 'No (N)'	System	09 Aug 2020 09:45:04

US3012073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:44:54', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '3b370d78-4344-45df-b02b-267e76190a02'	System	09 Aug 2020 09:45:04
User entered 'None (1)'	System	09 Aug 2020 09:45:04

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:45:02', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '3b370d78-4344-45df-b02b-267e76190a02'	System	09 Aug 2020 09:45:04
User entered '09 Aug 2020 04:45'	System	09 Aug 2020 09:45:04

FDA-CBER-2022-1614-0000514

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000515

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000516

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 4'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000517

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:12:12', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '52993914-d602-41ae-8ace-aaac02382803'	System	10 Aug 2020 02:18:49
User entered 'None (1)'	System	10 Aug 2020 02:18:49

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:14:13', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '52993914-d602-41ae-8ace-aaac02382803'	System	10 Aug 2020 02:18:49
User entered 'No (N)'	System	10 Aug 2020 02:18:49

FDA-CBER-2022-1614-0000519

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:14:16', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '52993914-d602-41ae-8ace-aaac02382803'	System	10 Aug 2020 02:18:49
User entered 'No (N)'	System	10 Aug 2020 02:18:49

US3012073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:52:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:18:37', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '52993914-d602-41ae-8ace-aaac02382803'	System	10 Aug 2020 02:18:49
User entered 'None (1)'	System	10 Aug 2020 02:18:49

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:18:44', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '52993914-d602-41ae-8ace-aaac02382803'	System	10 Aug 2020 02:18:49
User entered '09 Aug 2020 21:18'	System	10 Aug 2020 02:18:49

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000523

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000524

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 5'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000525

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:45:17', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '88a261fa-dc2d-4a34-b3a2-d21a141fb339'	System	11 Aug 2020 00:45:48
User entered 'None (1)'	System	11 Aug 2020 00:45:48

FDA-CBER-2022-1614-0000526

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:45:20', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '88a261fa-dc2d-4a34-b3a2-d21a141fb339'	System	11 Aug 2020 00:45:48
User entered 'No (N)'	System	11 Aug 2020 00:45:48

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:45:23', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '88a261fa-dc2d-4a34-b3a2-d21a141fb339'	System	11 Aug 2020 00:45:48
User entered 'No (N)'	System	11 Aug 2020 00:45:48

US3012073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:45:40', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '88a261fa-dc2d-4a34-b3a2-d21a141fb339'	System	11 Aug 2020 00:45:48
User entered 'None (1)'	System	11 Aug 2020 00:45:48

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:45:46', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '88a261fa-dc2d-4a34-b3a2-d21a141fb339'	System	11 Aug 2020 00:45:48
User entered '10 Aug 2020 19:45'	System	11 Aug 2020 00:45:48

FDA-CBER-2022-1614-0000530

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000531

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000532

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 6'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000533

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000534

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000535

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000536

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000537

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000538

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000539

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000540

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000541

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000542

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 7'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000543

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:17:47', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'dad4cbec-32b3-4f94-ad14-084251395993'	System	13 Aug 2020 03:18:09
User entered 'None (1)'	System	13 Aug 2020 03:18:09

FDA-CBER-2022-1614-0000544

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:17:50', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'dad4cbec-32b3-4f94-ad14-084251395993'	System	13 Aug 2020 03:18:09
User entered 'No (N)'	System	13 Aug 2020 03:18:09

FDA-CBER-2022-1614-0000545

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:17:54', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'dad4cbec-32b3-4f94-ad14-084251395993'	System	13 Aug 2020 03:18:09
User entered 'No (N)'	System	13 Aug 2020 03:18:09

FDA-CBER-2022-1614-0000546

US3012073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:52:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:17:57', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'dad4cbec-32b3-4f94-ad14-084251395993'	System	13 Aug 2020 03:18:09
User entered 'None (1)'	System	13 Aug 2020 03:18:09

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:18:06', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'dad4cbec-32b3-4f94-ad14-084251395993'	System	13 Aug 2020 03:18:09
User entered '12 Aug 2020 22:18'	System	13 Aug 2020 03:18:09

FDA-CBER-2022-1614-0000548

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000549

US3012073
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000550

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000551

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:14:36', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '0eb28a1a-3345-4e73-8553-587e12f911fd'	System	07 Aug 2020 01:15:24
User entered 'None (0)'	System	07 Aug 2020 01:15:24

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:14:43', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '0eb28a1a-3345-4e73-8553-587e12f911fd'	System	07 Aug 2020 01:15:24
User entered 'None (0)'	System	07 Aug 2020 01:15:24

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:14:49', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '0eb28a1a-3345-4e73-8553-587e12f911fd'	System	07 Aug 2020 01:15:24
User entered 'None (0)'	System	07 Aug 2020 01:15:24

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:14:54', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '0eb28a1a-3345-4e73-8553-587e12f911fd'	System	07 Aug 2020 01:15:24
User entered 'None (0)'	System	07 Aug 2020 01:15:24

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:14:57', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '0eb28a1a-3345-4e73-8553-587e12f911fd'	System	07 Aug 2020 01:15:24
User entered 'None (0)'	System	07 Aug 2020 01:15:24

FDA-CBER-2022-1614-0000556

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:15:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '0eb28a1a-3345-4e73-8553-587e12f911fd'	System	07 Aug 2020 01:15:24
User entered 'None (0)'	System	07 Aug 2020 01:15:24

FDA-CBER-2022-1614-0000557

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:15:14', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '0eb28a1a-3345-4e73-8553-587e12f911fd'	System	07 Aug 2020 01:15:24
User entered 'No (N)'	System	07 Aug 2020 01:15:24

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-06T20:15:22', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '0eb28a1a-3345-4e73-8553-587e12f911fd'	System	07 Aug 2020 01:15:24
User entered '06 Aug 2020 20:15'	System	07 Aug 2020 01:15:24

FDA-CBER-2022-1614-0000559

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Aug 2020 19:57'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000560

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Aug 2020 22:27'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000561

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 01:11:01

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000563

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000564

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000565

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000566

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000567

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000568

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000569

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000570

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Aug 2020 23:22'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000571

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000572

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 2'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000573

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:11:37', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '72be44cd-750f-4bb4-9b09-79bf9155f844'	System	08 Aug 2020 01:12:25
User entered 'None (0)'	System	08 Aug 2020 01:12:25

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:11:44', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '72be44cd-750f-4bb4-9b09-79bf9155f844'	System	08 Aug 2020 01:12:25
User entered 'None (0)'	System	08 Aug 2020 01:12:25

FDA-CBER-2022-1614-0000575

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:11:50', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '72be44cd-750f-4bb4-9b09-79bf9155f844'	System	08 Aug 2020 01:12:25
User entered 'None (0)'	System	08 Aug 2020 01:12:25

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:11:57', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '72be44cd-750f-4bb4-9b09-79bf9155f844'	System	08 Aug 2020 01:12:25
User entered 'None (0)'	System	08 Aug 2020 01:12:25

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:12:01', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '72be44cd-750f-4bb4-9b09-79bf9155f844'	System	08 Aug 2020 01:12:25
User entered 'None (0)'	System	08 Aug 2020 01:12:25

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:12:05', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '72be44cd-750f-4bb4-9b09-79bf9155f844'	System	08 Aug 2020 01:12:25
User entered 'None (0)'	System	08 Aug 2020 01:12:25

FDA-CBER-2022-1614-0000579

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:12:13', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '72be44cd-750f-4bb4-9b09-79bf9155f844'	System	08 Aug 2020 01:12:25
User entered 'No (N)'	System	08 Aug 2020 01:12:25

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-07T20:12:21', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '72be44cd-750f-4bb4-9b09-79bf9155f844'	System	08 Aug 2020 01:12:25
User entered '07 Aug 2020 20:12'	System	08 Aug 2020 01:12:25

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000582

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000583

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 3'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000584

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:48:09', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '324b0385-b88d-461f-8ba6-5b65a2a60256'	System	09 Aug 2020 09:49:02
User entered 'None (0)'	System	09 Aug 2020 09:49:02

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:48:19', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '324b0385-b88d-461f-8ba6-5b65a2a60256'	System	09 Aug 2020 09:49:02
User entered 'None (0)'	System	09 Aug 2020 09:49:02

FDA-CBER-2022-1614-0000586

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:48:27', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '324b0385-b88d-461f-8ba6-5b65a2a60256'	System	09 Aug 2020 09:49:02
User entered 'None (0)'	System	09 Aug 2020 09:49:02

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:48:35', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '324b0385-b88d-461f-8ba6-5b65a2a60256'	System	09 Aug 2020 09:49:02
User entered 'None (0)'	System	09 Aug 2020 09:49:02

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:48:38', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '324b0385-b88d-461f-8ba6-5b65a2a60256'	System	09 Aug 2020 09:49:02
User entered 'None (0)'	System	09 Aug 2020 09:49:02

FDA-CBER-2022-1614-0000589

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:48:42', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '324b0385-b88d-461f-8ba6-5b65a2a60256'	System	09 Aug 2020 09:49:02
User entered 'None (0)'	System	09 Aug 2020 09:49:02

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:48:51', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '324b0385-b88d-461f-8ba6-5b65a2a60256'	System	09 Aug 2020 09:49:02
User entered 'No (N)'	System	09 Aug 2020 09:49:02

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T04:49:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '324b0385-b88d-461f-8ba6-5b65a2a60256'	System	09 Aug 2020 09:49:02
User entered '09 Aug 2020 04:49'	System	09 Aug 2020 09:49:02

FDA-CBER-2022-1614-0000592

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000593

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000594

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 4'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000595

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:18:54', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '2ff80091-e8d4-4060-b47e-804deb1a25d7'	System	10 Aug 2020 02:19:20
User entered 'None (0)'	System	10 Aug 2020 02:19:20

FDA-CBER-2022-1614-0000596

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:18:58', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '2ff80091-e8d4-4060-b47e-804deb1a25d7'	System	10 Aug 2020 02:19:20
User entered 'None (0)'	System	10 Aug 2020 02:19:20

FDA-CBER-2022-1614-0000597

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:19:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '2ff80091-e8d4-4060-b47e-804deb1a25d7'	System	10 Aug 2020 02:19:20
User entered 'None (0)'	System	10 Aug 2020 02:19:20

FDA-CBER-2022-1614-0000598

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:19:03', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '2ff80091-e8d4-4060-b47e-804deb1a25d7'	System	10 Aug 2020 02:19:20
User entered 'None (0)'	System	10 Aug 2020 02:19:20

FDA-CBER-2022-1614-0000599

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:19:06', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '2ff80091-e8d4-4060-b47e-804deb1a25d7'	System	10 Aug 2020 02:19:20
User entered 'None (0)'	System	10 Aug 2020 02:19:20

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:19:09', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '2ff80091-e8d4-4060-b47e-804deb1a25d7'	System	10 Aug 2020 02:19:20
User entered 'None (0)'	System	10 Aug 2020 02:19:20

FDA-CBER-2022-1614-0000601

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:19:13', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '2ff80091-e8d4-4060-b47e-804deb1a25d7'	System	10 Aug 2020 02:19:20
User entered 'No (N)'	System	10 Aug 2020 02:19:20

FDA-CBER-2022-1614-0000602

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-09T21:19:19', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '2ff80091-e8d4-4060-b47e-804deb1a25d7'	System	10 Aug 2020 02:19:20
User entered '09 Aug 2020 21:19'	System	10 Aug 2020 02:19:20

FDA-CBER-2022-1614-0000603

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000604

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000605

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 5'	System	07 Aug 2020 01:11:01

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:45:51', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '749b5b60-37a8-48be-9d26-ab53eab0d55c'	System	11 Aug 2020 00:46:20
User entered 'None (0)'	System	11 Aug 2020 00:46:20

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:45:55', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '749b5b60-37a8-48be-9d26-ab53eab0d55c'	System	11 Aug 2020 00:46:20
User entered 'None (0)'	System	11 Aug 2020 00:46:20

FDA-CBER-2022-1614-0000608

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:45:57', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '749b5b60-37a8-48be-9d26-ab53eab0d55c'	System	11 Aug 2020 00:46:20
User entered 'None (0)'	System	11 Aug 2020 00:46:20

FDA-CBER-2022-1614-0000609

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:46:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '749b5b60-37a8-48be-9d26-ab53eab0d55c'	System	11 Aug 2020 00:46:20
User entered 'None (0)'	System	11 Aug 2020 00:46:20

FDA-CBER-2022-1614-0000610

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:46:02', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '749b5b60-37a8-48be-9d26-ab53eab0d55c'	System	11 Aug 2020 00:46:20
User entered 'None (0)'	System	11 Aug 2020 00:46:20

FDA-CBER-2022-1614-0000611

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:46:05', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '749b5b60-37a8-48be-9d26-ab53eab0d55c'	System	11 Aug 2020 00:46:20
User entered 'None (0)'	System	11 Aug 2020 00:46:20

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:46:12', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '749b5b60-37a8-48be-9d26-ab53eab0d55c'	System	11 Aug 2020 00:46:20
User entered 'No (N)'	System	11 Aug 2020 00:46:20

FDA-CBER-2022-1614-0000613

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-10T19:46:18', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '749b5b60-37a8-48be-9d26-ab53eab0d55c'	System	11 Aug 2020 00:46:20
User entered '10 Aug 2020 19:46'	System	11 Aug 2020 00:46:20

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000615

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000616

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 6'	System	07 Aug 2020 01:11:01

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000618

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000619

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000620

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000621

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000622

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000623

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000624

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000625

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000626

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 7'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000628

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:18:14', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '20f388d1-37bd-4507-b36e-e1b88cdb528a'	System	13 Aug 2020 03:18:40
User entered 'None (0)'	System	13 Aug 2020 03:18:40

FDA-CBER-2022-1614-0000629

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:18:19', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '20f388d1-37bd-4507-b36e-e1b88cdb528a'	System	13 Aug 2020 03:18:40
User entered 'None (0)'	System	13 Aug 2020 03:18:40

FDA-CBER-2022-1614-0000630

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:18:22', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '20f388d1-37bd-4507-b36e-e1b88cdb528a'	System	13 Aug 2020 03:18:40
User entered 'None (0)'	System	13 Aug 2020 03:18:40

FDA-CBER-2022-1614-0000631

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:18:24', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '20f388d1-37bd-4507-b36e-e1b88cdb528a'	System	13 Aug 2020 03:18:40
User entered 'None (0)'	System	13 Aug 2020 03:18:40

FDA-CBER-2022-1614-0000632

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:18:27', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '20f388d1-37bd-4507-b36e-e1b88cdb528a'	System	13 Aug 2020 03:18:40
User entered 'None (0)'	System	13 Aug 2020 03:18:40

FDA-CBER-2022-1614-0000633

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:18:29', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '20f388d1-37bd-4507-b36e-e1b88cdb528a'	System	13 Aug 2020 03:18:40
User entered 'None (0)'	System	13 Aug 2020 03:18:40

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:18:34', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '20f388d1-37bd-4507-b36e-e1b88cdb528a'	System	13 Aug 2020 03:18:40
User entered 'No (N)'	System	13 Aug 2020 03:18:40

FDA-CBER-2022-1614-0000635

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-08-12T22:18:39', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '20f388d1-37bd-4507-b36e-e1b88cdb528a'	System	13 Aug 2020 03:18:40
User entered '12 Aug 2020 22:18'	System	13 Aug 2020 03:18:40

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000637

US3012073
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000638

US3012073
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	17 Aug 2020 12:22:21

US3012073
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '15 Aug 2020'	Tambra Dora (b) (4) (b) (4)	17 Aug 2020 12:22:21

US3012073
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	17 Aug 2020 12:22:21

US3012073
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Tambra Dora (b) (4) (b) (4)	17 Aug 2020 12:22:21

US3012073
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	17 Aug 2020 12:22:25

US3012073
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	17 Aug 2020 12:22:25

FDA-CBER-2022-1614-0000644

US3012073
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	20 Aug 2020 22:27:53

US3012073
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '20 Aug 2020'	Tambra Dora (b) (4) (b) (4)	20 Aug 2020 22:27:53

FDA-CBER-2022-1614-0000646

US3012073
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	20 Aug 2020 22:27:53

US3012073
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Tambra Dora (b) (4) (b) (4)	20 Aug 2020 22:27:53

US3012073
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	20 Aug 2020 22:27:57

US3012073
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	20 Aug 2020 22:27:57

US3012073
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	27 Aug 2020 22:30:23

US3012073
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '27 Aug 2020'	Tambra Dora (b) (4) (b) (4)	27 Aug 2020 22:30:23

FDA-CBER-2022-1614-0000652

US3012073
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	27 Aug 2020 22:30:23

US3012073
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Tambra Dora (b) (4) (b) (4)	27 Aug 2020 22:30:23

US3012073
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	27 Aug 2020 22:30:27

US3012073
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	27 Aug 2020 22:30:27

FDA-CBER-2022-1614-0000656

US3012073
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:27:58

FDA-CBER-2022-1614-0000657

US3012073
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '03 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:27:58

FDA-CBER-2022-1614-0000658

US3012073
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:27:58

FDA-CBER-2022-1614-0000659

US3012073
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'VISIT2'	System	03 Sep 2020 21:27:58

FDA-CBER-2022-1614-0000660

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000661

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000662

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '03 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000663

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '14:56'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000664

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '03 Sep 2020 14:56'	System	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000665

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '98.1' F	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000666

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000667

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000668

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '72'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:16

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'bpm'	System	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000670

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '12' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 14:58:33
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000671

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'breaths/min'	System	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000672

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '138'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000673

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000674

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '83'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000675

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	03 Sep 2020 21:28:16

FDA-CBER-2022-1614-0000676

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000677

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000678

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '03 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000679

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '17:07'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000680

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '03 Sep 2020 17:07'	System	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000681

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '98.2' F	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000682

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000683

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000684

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '69'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000685

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'bpm'	System	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000686

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000687

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'breaths/min'	System	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000688

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '137'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000689

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000690

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '76'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000691

US3012073
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	03 Sep 2020 23:16:49

FDA-CBER-2022-1614-0000692

US3012073
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:26

FDA-CBER-2022-1614-0000693

US3012073
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '03 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:26

FDA-CBER-2022-1614-0000694

US3012073
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000695

US3012073
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Katherine Davis (b) (4) (b) (4)	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000696

US3012073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Katherine Davis (b) (4) (b) (4)	03 Sep 2020 22:01:29

US3012073
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000698

US3012073
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '3 Sep 2020'	Katherine Davis (b) (4) (b) (4)	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000699

US3012073
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '16:29'	Katherine Davis (b) (4) (b) (4)	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000700

US3012073
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '3 Sep 2020 16:29'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000701

US3012073
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Left Arm (LEFT ARM)'	Katherine Davis (b) (4) (b) (4)	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000702

US3012073
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'ONCE'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000703

US3012073
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000704

US3012073
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:40

FDA-CBER-2022-1614-0000705

US3012073
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '03 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:40

FDA-CBER-2022-1614-0000706

US3012073
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '15:07'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:40

US3012073
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '03 Sep 2020 15:07'	System	03 Sep 2020 21:28:40

FDA-CBER-2022-1614-0000708

US3012073
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 14:52:36
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '03 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:54

FDA-CBER-2022-1614-0000709

US3012073
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:52:36
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:54

FDA-CBER-2022-1614-0000710

US3012073
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:52:36
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:54

FDA-CBER-2022-1614-0000711

US3012073
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:52:36
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '15:42'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:54

FDA-CBER-2022-1614-0000712

US3012073
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:52:36
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '03 Sep 2020 15:42'	System	03 Sep 2020 21:28:54

FDA-CBER-2022-1614-0000713

US3012073
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:52:36
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:54

FDA-CBER-2022-1614-0000714

US3012073
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:52:36
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:54

FDA-CBER-2022-1614-0000715

US3012073
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:52:36
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:54

US3012073
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:52:36
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered empty.	System	03 Sep 2020 21:28:54

FDA-CBER-2022-1614-0000717

US3012073
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:28:57

FDA-CBER-2022-1614-0000718

US3012073
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '1'	System	03 Sep 2020 21:28:57

FDA-CBER-2022-1614-0000719

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000720

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:02:19', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '742a583b-35e1-490f-8eb6-3e47f3ccd097'	System	03 Sep 2020 22:02:45
User entered 'Yes (Y)'	System	03 Sep 2020 22:02:45

FDA-CBER-2022-1614-0000721

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:02:29', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '742a583b-35e1-490f-8eb6-3e47f3ccd097'	System	03 Sep 2020 22:02:45
User entered '98.2'	System	03 Sep 2020 22:02:45

FDA-CBER-2022-1614-0000722

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:02:33', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '742a583b-35e1-490f-8eb6-3e47f3ccd097'	System	03 Sep 2020 22:02:45
User entered 'No (N)'	System	03 Sep 2020 22:02:45

FDA-CBER-2022-1614-0000723

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:02:42', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '742a583b-35e1-490f-8eb6-3e47f3ccd097'	System	03 Sep 2020 22:02:45
User entered '03 Sep 2020 17:02'	System	03 Sep 2020 22:02:45

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '03 Sep 2020 16:49'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000725

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '03 Sep 2020 19:19'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000726

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 22:01:29

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6))	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:14:30', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8e1c38e8-551b-4ff3-a246-fdf0c8a12ea9'	System	04 Sep 2020 01:15:01
User entered 'Yes (Y)'	System	04 Sep 2020 01:15:01

FDA-CBER-2022-1614-0000728

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:14:44', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8e1c38e8-551b-4ff3-a246-fdf0c8a12ea9'	System	04 Sep 2020 01:15:01
User entered '97.0'	System	04 Sep 2020 01:15:01

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:14:48', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8e1c38e8-551b-4ff3-a246-fdf0c8a12ea9'	System	04 Sep 2020 01:15:01
User entered 'No (N)'	System	04 Sep 2020 01:15:01

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:14:57', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8e1c38e8-551b-4ff3-a246-fdf0c8a12ea9'	System	04 Sep 2020 01:15:01
User entered '03 Sep 2020 20:14'	System	04 Sep 2020 01:15:01

FDA-CBER-2022-1614-0000731

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '03 Sep 2020 20:14'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000732

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000733

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 2'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000734

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:19:42', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '3b59793f-3c4c-4daa-af20-a4b9a2b0b768'	System	05 Sep 2020 02:20:08
User entered 'Yes (Y)'	System	05 Sep 2020 02:20:08

FDA-CBER-2022-1614-0000735

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:19:55', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '3b59793f-3c4c-4daa-af20-a4b9a2b0b768'	System	05 Sep 2020 02:20:08
User entered '97.3'	System	05 Sep 2020 02:20:08

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:19:59', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '3b59793f-3c4c-4daa-af20-a4b9a2b0b768'	System	05 Sep 2020 02:20:08
User entered 'No (N)'	System	05 Sep 2020 02:20:08

FDA-CBER-2022-1614-0000737

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:20:05', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '3b59793f-3c4c-4daa-af20-a4b9a2b0b768'	System	05 Sep 2020 02:20:08
User entered '04 Sep 2020 21:20'	System	05 Sep 2020 02:20:08

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000739

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000740

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 3'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000741

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:38:51', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '43bfabe5-6d15-4939-8a8e-0f382ec86e09'	System	06 Sep 2020 00:39:13
User entered 'Yes (Y)'	System	06 Sep 2020 00:39:13

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:38:58', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '43bfabe5-6d15-4939-8a8e-0f382ec86e09'	System	06 Sep 2020 00:39:13
User entered '97.7'	System	06 Sep 2020 00:39:13

FDA-CBER-2022-1614-0000743

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:39:03', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '43bfabe5-6d15-4939-8a8e-0f382ec86e09'	System	06 Sep 2020 00:39:13
User entered 'No (N)'	System	06 Sep 2020 00:39:13

FDA-CBER-2022-1614-0000744

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:39:09', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '43bfabe5-6d15-4939-8a8e-0f382ec86e09'	System	06 Sep 2020 00:39:13
User entered '05 Sep 2020 19:39'	System	06 Sep 2020 00:39:13

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000746

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000747

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 4'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000748

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000749

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000750

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000751

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000752

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000753

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000754

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000755

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000756

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 5'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000757

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:16:23', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '4378ceab-bc20-4d0e-860e-24a2d656019f'	System	08 Sep 2020 02:16:39
User entered 'Yes (Y)'	System	08 Sep 2020 02:16:39

FDA-CBER-2022-1614-0000758

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:16:29', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '4378ceab-bc20-4d0e-860e-24a2d656019f'	System	08 Sep 2020 02:16:39
User entered '96.4'	System	08 Sep 2020 02:16:39

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:16:32', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '4378ceab-bc20-4d0e-860e-24a2d656019f'	System	08 Sep 2020 02:16:39
User entered 'No (N)'	System	08 Sep 2020 02:16:39

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:16:35', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '4378ceab-bc20-4d0e-860e-24a2d656019f'	System	08 Sep 2020 02:16:39
User entered '07 Sep 2020 21:16'	System	08 Sep 2020 02:16:39

FDA-CBER-2022-1614-0000761

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000762

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000763

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 6'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000764

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:19:55', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c39fccec-b1fd-45de-bd3a-aa14ec760ce7'	System	09 Sep 2020 03:20:15
User entered 'Yes (Y)'	System	09 Sep 2020 03:20:15

FDA-CBER-2022-1614-0000765

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:02', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c39fccec-b1fd-45de-bd3a-aa14ec760ce7'	System	09 Sep 2020 03:20:15
User entered '97.2'	System	09 Sep 2020 03:20:15

FDA-CBER-2022-1614-0000766

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:06', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c39fccec-b1fd-45de-bd3a-aa14ec760ce7'	System	09 Sep 2020 03:20:15
User entered 'No (N)'	System	09 Sep 2020 03:20:15

FDA-CBER-2022-1614-0000767

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:11', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c39fccec-b1fd-45de-bd3a-aa14ec760ce7'	System	09 Sep 2020 03:20:15
User entered '08 Sep 2020 22:20'	System	09 Sep 2020 03:20:15

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000769

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000770

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 7'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000771

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:18:33', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'f549809f-293b-41d3-a045-8d2493791abc'	System	10 Sep 2020 04:18:52
User entered 'Yes (Y)'	System	10 Sep 2020 04:18:52

FDA-CBER-2022-1614-0000772

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:18:39', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'f549809f-293b-41d3-a045-8d2493791abc'	System	10 Sep 2020 04:18:52
User entered '96.4'	System	10 Sep 2020 04:18:52

FDA-CBER-2022-1614-0000773

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:18:43', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'f549809f-293b-41d3-a045-8d2493791abc'	System	10 Sep 2020 04:18:52
User entered 'No (N)'	System	10 Sep 2020 04:18:52

FDA-CBER-2022-1614-0000774

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:18:47', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'f549809f-293b-41d3-a045-8d2493791abc'	System	10 Sep 2020 04:18:52
User entered '09 Sep 2020 23:18'	System	10 Sep 2020 04:18:52

FDA-CBER-2022-1614-0000775

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000776

US3012073
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000777

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 22:01:29

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:02:48', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '965e4f2d-3d86-4419-8aac-2cb4a11923c6'	System	03 Sep 2020 22:03:12
User entered 'None (1)'	System	03 Sep 2020 22:03:12

FDA-CBER-2022-1614-0000779

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:02:53', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '965e4f2d-3d86-4419-8aac-2cb4a11923c6'	System	03 Sep 2020 22:03:12
User entered 'No (N)'	System	03 Sep 2020 22:03:12

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:02:58', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '965e4f2d-3d86-4419-8aac-2cb4a11923c6'	System	03 Sep 2020 22:03:12
User entered 'No (N)'	System	03 Sep 2020 22:03:12

FDA-CBER-2022-1614-0000781

US3012073

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:52:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:03:04', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '965e4f2d-3d86-4419-8aac-2cb4a11923c6'	System	03 Sep 2020 22:03:12
User entered 'None (1)'	System	03 Sep 2020 22:03:12

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:03:10', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '965e4f2d-3d86-4419-8aac-2cb4a11923c6'	System	03 Sep 2020 22:03:12
User entered '03 Sep 2020 17:03'	System	03 Sep 2020 22:03:12

FDA-CBER-2022-1614-0000783

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '03 Sep 2020 16:49'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000784

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '03 Sep 2020 19:19'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000785

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000786

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:15:02', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '01e66fa6-ab97-4ae0-b188-c6f083d3ca7e'	System	04 Sep 2020 01:15:40
User entered 'None (1)'	System	04 Sep 2020 01:15:40

FDA-CBER-2022-1614-0000787

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:15:14', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '01e66fa6-ab97-4ae0-b188-c6f083d3ca7e'	System	04 Sep 2020 01:15:40
User entered 'No (N)'	System	04 Sep 2020 01:15:40

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:15:17', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '01e66fa6-ab97-4ae0-b188-c6f083d3ca7e'	System	04 Sep 2020 01:15:40
User entered 'No (N)'	System	04 Sep 2020 01:15:40

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:15:21', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '01e66fa6-ab97-4ae0-b188-c6f083d3ca7e'	System	04 Sep 2020 01:15:40
User entered 'None (1)'	System	04 Sep 2020 01:15:40

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:15:34', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '01e66fa6-ab97-4ae0-b188-c6f083d3ca7e'	System	04 Sep 2020 01:15:40
User entered '03 Sep 2020 20:15'	System	04 Sep 2020 01:15:40

FDA-CBER-2022-1614-0000791

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '03 Sep 2020 20:14'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000792

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000793

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 2'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000794

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:20:11', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '7403b358-a9c5-4ff5-a0cd-add3d88c5c65'	System	05 Sep 2020 02:20:55
User entered 'None (1)'	System	05 Sep 2020 02:20:55

FDA-CBER-2022-1614-0000795

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:20:16', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '7403b358-a9c5-4ff5-a0cd-add3d88c5c65'	System	05 Sep 2020 02:20:55
User entered 'No (N)'	System	05 Sep 2020 02:20:55

FDA-CBER-2022-1614-0000796

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:20:19', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '7403b358-a9c5-4ff5-a0cd-add3d88c5c65'	System	05 Sep 2020 02:20:55
User entered 'No (N)'	System	05 Sep 2020 02:20:55

FDA-CBER-2022-1614-0000797

US3012073

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:52:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:20:45', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '7403b358-a9c5-4ff5-a0cd-add3d88c5c65'	System	05 Sep 2020 02:20:55
User entered 'None (1)'	System	05 Sep 2020 02:20:55

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:20:53', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '7403b358-a9c5-4ff5-a0cd-add3d88c5c65'	System	05 Sep 2020 02:20:55
User entered '04 Sep 2020 21:20'	System	05 Sep 2020 02:20:55

FDA-CBER-2022-1614-0000799

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000800

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000801

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 3'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000802

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:39:14', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '21a24e80-46fa-45fe-9875-4151f807cbbc'	System	06 Sep 2020 00:40:05
User entered 'None (1)'	System	06 Sep 2020 00:40:05

FDA-CBER-2022-1614-0000803

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:39:16', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '21a24e80-46fa-45fe-9875-4151f807cbbc'	System	06 Sep 2020 00:40:05
User entered 'No (N)'	System	06 Sep 2020 00:40:05

FDA-CBER-2022-1614-0000804

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:39:21', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '21a24e80-46fa-45fe-9875-4151f807cbbc'	System	06 Sep 2020 00:40:05
User entered 'No (N)'	System	06 Sep 2020 00:40:05

US3012073

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:52:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:39:24', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '21a24e80-46fa-45fe-9875-4151f807cbbc'	System	06 Sep 2020 00:40:05
User entered 'None (1)'	System	06 Sep 2020 00:40:05

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:39:59', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '21a24e80-46fa-45fe-9875-4151f807cbbc'	System	06 Sep 2020 00:40:05
User entered '05 Sep 2020 19:39'	System	06 Sep 2020 00:40:05

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000808

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000809

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 4'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000810

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000811

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000812

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000813

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000814

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000815

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000816

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000817

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000818

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000819

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 5'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000820

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:16:45', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '46a7835a-5ce2-4f79-9276-1709d8b3bd1e'	System	08 Sep 2020 02:17:04
User entered 'None (1)'	System	08 Sep 2020 02:17:04

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:16:47', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '46a7835a-5ce2-4f79-9276-1709d8b3bd1e'	System	08 Sep 2020 02:17:04
User entered 'No (N)'	System	08 Sep 2020 02:17:04

FDA-CBER-2022-1614-0000822

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:16:50', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '46a7835a-5ce2-4f79-9276-1709d8b3bd1e'	System	08 Sep 2020 02:17:04
User entered 'No (N)'	System	08 Sep 2020 02:17:04

FDA-CBER-2022-1614-0000823

US3012073

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:52:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:16:53', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '46a7835a-5ce2-4f79-9276-1709d8b3bd1e'	System	08 Sep 2020 02:17:04
User entered 'None (1)'	System	08 Sep 2020 02:17:04

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:17:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '46a7835a-5ce2-4f79-9276-1709d8b3bd1e'	System	08 Sep 2020 02:17:04
User entered '07 Sep 2020 21:17'	System	08 Sep 2020 02:17:04

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000826

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000827

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 6'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000828

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:16', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '11cd2270-5931-4eaa-ae6a-811513d39046'	System	09 Sep 2020 03:20:35
User entered 'None (1)'	System	09 Sep 2020 03:20:35

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:20', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '11cd2270-5931-4eaa-ae6a-811513d39046'	System	09 Sep 2020 03:20:35
User entered 'No (N)'	System	09 Sep 2020 03:20:35

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:22', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '11cd2270-5931-4eaa-ae6a-811513d39046'	System	09 Sep 2020 03:20:35
User entered 'No (N)'	System	09 Sep 2020 03:20:35

FDA-CBER-2022-1614-0000831

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:25', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '11cd2270-5931-4eaa-ae6a-811513d39046'	System	09 Sep 2020 03:20:35
User entered 'None (1)'	System	09 Sep 2020 03:20:35

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:31', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '11cd2270-5931-4eaa-ae6a-811513d39046'	System	09 Sep 2020 03:20:35
User entered '08 Sep 2020 22:20'	System	09 Sep 2020 03:20:35

FDA-CBER-2022-1614-0000833

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000834

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000835

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 7'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000836

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:18:52', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9b3a99d8-cdfd-427e-b5f4-e2143d68980a'	System	10 Sep 2020 04:19:18
User entered 'None (1)'	System	10 Sep 2020 04:19:18

FDA-CBER-2022-1614-0000837

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:18:54', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9b3a99d8-cdfd-427e-b5f4-e2143d68980a'	System	10 Sep 2020 04:19:18
User entered 'No (N)'	System	10 Sep 2020 04:19:18

FDA-CBER-2022-1614-0000838

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:19:07', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9b3a99d8-cdfd-427e-b5f4-e2143d68980a'	System	10 Sep 2020 04:19:18
User entered 'No (N)'	System	10 Sep 2020 04:19:18

FDA-CBER-2022-1614-0000839

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:19:10', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9b3a99d8-cdfd-427e-b5f4-e2143d68980a'	System	10 Sep 2020 04:19:18
User entered 'None (1)'	System	10 Sep 2020 04:19:18

FDA-CBER-2022-1614-0000840

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:19:15', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9b3a99d8-cdfd-427e-b5f4-e2143d68980a'	System	10 Sep 2020 04:19:18
User entered '09 Sep 2020 23:19'	System	10 Sep 2020 04:19:18

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000842

US3012073
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000843

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000844

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:03:16', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9cc6e8e6-0c21-45e4-9ada-e550433cee64'	System	03 Sep 2020 22:03:41
User entered 'None (0)'	System	03 Sep 2020 22:03:41

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:03:20', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9cc6e8e6-0c21-45e4-9ada-e550433cee64'	System	03 Sep 2020 22:03:41
User entered 'None (0)'	System	03 Sep 2020 22:03:41

FDA-CBER-2022-1614-0000846

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:03:24', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9cc6e8e6-0c21-45e4-9ada-e550433cee64'	System	03 Sep 2020 22:03:41
User entered 'None (0)'	System	03 Sep 2020 22:03:41

FDA-CBER-2022-1614-0000847

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:03:26', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9cc6e8e6-0c21-45e4-9ada-e550433cee64'	System	03 Sep 2020 22:03:41
User entered 'None (0)'	System	03 Sep 2020 22:03:41

FDA-CBER-2022-1614-0000848

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:03:28', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9cc6e8e6-0c21-45e4-9ada-e550433cee64'	System	03 Sep 2020 22:03:41
User entered 'None (0)'	System	03 Sep 2020 22:03:41

FDA-CBER-2022-1614-0000849

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:03:29', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9cc6e8e6-0c21-45e4-9ada-e550433cee64'	System	03 Sep 2020 22:03:41
User entered 'None (0)'	System	03 Sep 2020 22:03:41

FDA-CBER-2022-1614-0000850

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:03:32', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9cc6e8e6-0c21-45e4-9ada-e550433cee64'	System	03 Sep 2020 22:03:41
User entered 'No (N)'	System	03 Sep 2020 22:03:41

FDA-CBER-2022-1614-0000851

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T17:03:38', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9cc6e8e6-0c21-45e4-9ada-e550433cee64'	System	03 Sep 2020 22:03:41
User entered '03 Sep 2020 17:03'	System	03 Sep 2020 22:03:41

FDA-CBER-2022-1614-0000852

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '03 Sep 2020 16:49'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000853

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '03 Sep 2020 19:19'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000854

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000855

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:15:42', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '18c8bf16-e2e3-4a8c-8a68-fbd0fea064dc'	System	04 Sep 2020 01:16:19
User entered 'None (0)'	System	04 Sep 2020 01:16:19

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:15:45', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '18c8bf16-e2e3-4a8c-8a68-fbd0fea064dc'	System	04 Sep 2020 01:16:19
User entered 'None (0)'	System	04 Sep 2020 01:16:19

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:15:53', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '18c8bf16-e2e3-4a8c-8a68-fbd0fea064dc'	System	04 Sep 2020 01:16:19
User entered 'None (0)'	System	04 Sep 2020 01:16:19

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:15:56', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '18c8bf16-e2e3-4a8c-8a68-fbd0fea064dc'	System	04 Sep 2020 01:16:19
User entered 'None (0)'	System	04 Sep 2020 01:16:19

FDA-CBER-2022-1614-0000859

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:15:58', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '18c8bf16-e2e3-4a8c-8a68-fbd0fea064dc'	System	04 Sep 2020 01:16:19
User entered 'None (0)'	System	04 Sep 2020 01:16:19

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:16:01', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '18c8bf16-e2e3-4a8c-8a68-fbd0fea064dc'	System	04 Sep 2020 01:16:19
User entered 'None (0)'	System	04 Sep 2020 01:16:19

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:16:08', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '18c8bf16-e2e3-4a8c-8a68-fbd0fea064dc'	System	04 Sep 2020 01:16:19
User entered 'No (N)'	System	04 Sep 2020 01:16:19

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-03T20:16:14', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '18c8bf16-e2e3-4a8c-8a68-fbd0fea064dc'	System	04 Sep 2020 01:16:19
User entered '03 Sep 2020 20:16'	System	04 Sep 2020 01:16:19

FDA-CBER-2022-1614-0000863

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '03 Sep 2020 20:14'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000864

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000865

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 2'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000866

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:21:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd8445b3b-b3fb-4199-8ec8-c23a35a20a87'	System	05 Sep 2020 02:21:25
User entered 'None (0)'	System	05 Sep 2020 02:21:25

FDA-CBER-2022-1614-0000867

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:21:02', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd8445b3b-b3fb-4199-8ec8-c23a35a20a87'	System	05 Sep 2020 02:21:25
User entered 'None (0)'	System	05 Sep 2020 02:21:25

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:21:05', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd8445b3b-b3fb-4199-8ec8-c23a35a20a87'	System	05 Sep 2020 02:21:25
User entered 'None (0)'	System	05 Sep 2020 02:21:25

FDA-CBER-2022-1614-0000869

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:21:07', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd8445b3b-b3fb-4199-8ec8-c23a35a20a87'	System	05 Sep 2020 02:21:25
User entered 'None (0)'	System	05 Sep 2020 02:21:25

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:21:09', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd8445b3b-b3fb-4199-8ec8-c23a35a20a87'	System	05 Sep 2020 02:21:25
User entered 'None (0)'	System	05 Sep 2020 02:21:25

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:21:11', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd8445b3b-b3fb-4199-8ec8-c23a35a20a87'	System	05 Sep 2020 02:21:25
User entered 'None (0)'	System	05 Sep 2020 02:21:25

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:21:15', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd8445b3b-b3fb-4199-8ec8-c23a35a20a87'	System	05 Sep 2020 02:21:25
User entered 'No (N)'	System	05 Sep 2020 02:21:25

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-04T21:21:19', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd8445b3b-b3fb-4199-8ec8-c23a35a20a87'	System	05 Sep 2020 02:21:25
User entered '04 Sep 2020 21:21'	System	05 Sep 2020 02:21:25

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000875

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000876

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 3'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000877

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:40:05', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9d5bacfe-2893-4724-8a97-f103e290209b'	System	06 Sep 2020 00:40:32
User entered 'None (0)'	System	06 Sep 2020 00:40:32

FDA-CBER-2022-1614-0000878

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:40:07', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9d5bacfe-2893-4724-8a97-f103e290209b'	System	06 Sep 2020 00:40:32
User entered 'None (0)'	System	06 Sep 2020 00:40:32

FDA-CBER-2022-1614-0000879

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:40:09', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9d5bacfe-2893-4724-8a97-f103e290209b'	System	06 Sep 2020 00:40:32
User entered 'None (0)'	System	06 Sep 2020 00:40:32

FDA-CBER-2022-1614-0000880

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:40:12', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9d5bacfe-2893-4724-8a97-f103e290209b'	System	06 Sep 2020 00:40:32
User entered 'None (0)'	System	06 Sep 2020 00:40:32

FDA-CBER-2022-1614-0000881

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:40:15', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9d5bacfe-2893-4724-8a97-f103e290209b'	System	06 Sep 2020 00:40:32
User entered 'None (0)'	System	06 Sep 2020 00:40:32

FDA-CBER-2022-1614-0000882

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:40:17', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9d5bacfe-2893-4724-8a97-f103e290209b'	System	06 Sep 2020 00:40:32
User entered 'None (0)'	System	06 Sep 2020 00:40:32

FDA-CBER-2022-1614-0000883

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:40:20', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9d5bacfe-2893-4724-8a97-f103e290209b'	System	06 Sep 2020 00:40:32
User entered 'No (N)'	System	06 Sep 2020 00:40:32

FDA-CBER-2022-1614-0000884

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-05T19:40:26', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '9d5bacfe-2893-4724-8a97-f103e290209b'	System	06 Sep 2020 00:40:32
User entered '05 Sep 2020 19:40'	System	06 Sep 2020 00:40:32

FDA-CBER-2022-1614-0000885

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000886

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000887

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 4'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000888

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000889

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000890

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000891

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000892

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000893

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000894

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000895

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21

FDA-CBER-2022-1614-0000896

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000897

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000898

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 5'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000899

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:17:05', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8f4754ec-477f-4b7f-92c8-27ef9498d143'	System	08 Sep 2020 02:17:29
User entered 'None (0)'	System	08 Sep 2020 02:17:29

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:17:08', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8f4754ec-477f-4b7f-92c8-27ef9498d143'	System	08 Sep 2020 02:17:29
User entered 'None (0)'	System	08 Sep 2020 02:17:29

FDA-CBER-2022-1614-0000901

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:17:10', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8f4754ec-477f-4b7f-92c8-27ef9498d143'	System	08 Sep 2020 02:17:29
User entered 'None (0)'	System	08 Sep 2020 02:17:29

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:17:12', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8f4754ec-477f-4b7f-92c8-27ef9498d143'	System	08 Sep 2020 02:17:29
User entered 'None (0)'	System	08 Sep 2020 02:17:29

FDA-CBER-2022-1614-0000903

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:17:14', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8f4754ec-477f-4b7f-92c8-27ef9498d143'	System	08 Sep 2020 02:17:29
User entered 'None (0)'	System	08 Sep 2020 02:17:29

FDA-CBER-2022-1614-0000904

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:17:16', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8f4754ec-477f-4b7f-92c8-27ef9498d143'	System	08 Sep 2020 02:17:29
User entered 'None (0)'	System	08 Sep 2020 02:17:29

FDA-CBER-2022-1614-0000905

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:17:19', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8f4754ec-477f-4b7f-92c8-27ef9498d143'	System	08 Sep 2020 02:17:29
User entered 'No (N)'	System	08 Sep 2020 02:17:29

FDA-CBER-2022-1614-0000906

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-07T21:17:23', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '8f4754ec-477f-4b7f-92c8-27ef9498d143'	System	08 Sep 2020 02:17:29
User entered '07 Sep 2020 21:17'	System	08 Sep 2020 02:17:29

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000908

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000909

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 6'	System	03 Sep 2020 22:01:29

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:38', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cfda3a03-6971-493b-b19f-67778dfdef23'	System	09 Sep 2020 03:21:04
User entered 'None (0)'	System	09 Sep 2020 03:21:04

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:40', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cfda3a03-6971-493b-b19f-67778dfdef23'	System	09 Sep 2020 03:21:04
User entered 'None (0)'	System	09 Sep 2020 03:21:04

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:43', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cfda3a03-6971-493b-b19f-67778dfdef23'	System	09 Sep 2020 03:21:04
User entered 'None (0)'	System	09 Sep 2020 03:21:04

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:45', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cfda3a03-6971-493b-b19f-67778dfdef23'	System	09 Sep 2020 03:21:04
User entered 'None (0)'	System	09 Sep 2020 03:21:04

FDA-CBER-2022-1614-0000914

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:48', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cfda3a03-6971-493b-b19f-67778dfdef23'	System	09 Sep 2020 03:21:04
User entered 'None (0)'	System	09 Sep 2020 03:21:04

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:50', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cfda3a03-6971-493b-b19f-67778dfdef23'	System	09 Sep 2020 03:21:04
User entered 'None (0)'	System	09 Sep 2020 03:21:04

FDA-CBER-2022-1614-0000916

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:52', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cfda3a03-6971-493b-b19f-67778dfdef23'	System	09 Sep 2020 03:21:04
User entered 'No (N)'	System	09 Sep 2020 03:21:04

FDA-CBER-2022-1614-0000917

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-08T22:20:58', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'cfda3a03-6971-493b-b19f-67778dfdef23'	System	09 Sep 2020 03:21:04
User entered '08 Sep 2020 22:20'	System	09 Sep 2020 03:21:04

FDA-CBER-2022-1614-0000918

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000919

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000920

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	03 Sep 2020 22:01:29
User entered 'Day 7'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000921

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:19:21', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c89888af-8ad1-4e7c-8970-ca7bf1ac463d'	System	10 Sep 2020 04:19:47
User entered 'None (0)'	System	10 Sep 2020 04:19:47

FDA-CBER-2022-1614-0000922

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:19:24', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c89888af-8ad1-4e7c-8970-ca7bf1ac463d'	System	10 Sep 2020 04:19:47
User entered 'None (0)'	System	10 Sep 2020 04:19:47

FDA-CBER-2022-1614-0000923

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:19:26', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c89888af-8ad1-4e7c-8970-ca7bf1ac463d'	System	10 Sep 2020 04:19:47
User entered 'None (0)'	System	10 Sep 2020 04:19:47

FDA-CBER-2022-1614-0000924

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:19:28', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c89888af-8ad1-4e7c-8970-ca7bf1ac463d'	System	10 Sep 2020 04:19:47
User entered 'None (0)'	System	10 Sep 2020 04:19:47

FDA-CBER-2022-1614-0000925

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:19:30', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c89888af-8ad1-4e7c-8970-ca7bf1ac463d'	System	10 Sep 2020 04:19:47
User entered 'None (0)'	System	10 Sep 2020 04:19:47

FDA-CBER-2022-1614-0000926

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:19:33', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c89888af-8ad1-4e7c-8970-ca7bf1ac463d'	System	10 Sep 2020 04:19:47
User entered 'None (0)'	System	10 Sep 2020 04:19:47

FDA-CBER-2022-1614-0000927

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:19:37', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c89888af-8ad1-4e7c-8970-ca7bf1ac463d'	System	10 Sep 2020 04:19:47
User entered 'No (N)'	System	10 Sep 2020 04:19:47

FDA-CBER-2022-1614-0000928

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-09-09T23:19:43', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c89888af-8ad1-4e7c-8970-ca7bf1ac463d'	System	10 Sep 2020 04:19:47
User entered '09 Sep 2020 23:19'	System	10 Sep 2020 04:19:47

FDA-CBER-2022-1614-0000929

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000930

US3012073
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:52:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 22:01:29

FDA-CBER-2022-1614-0000931

US3012073
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	15 Sep 2020 00:02:47

FDA-CBER-2022-1614-0000932

US3012073
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 05:44:56
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct as entered ' (Site from System).	Tambra Dora (b) (4) (b) (4)	15 Sep 2020 00:03:02
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Sep 2020 00:02:47
User entered '14 Sep 2020'	Tambra Dora (b) (4) (b) (4)	15 Sep 2020 00:02:47

US3012073
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	15 Sep 2020 00:02:47

FDA-CBER-2022-1614-0000934

US3012073
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Tambra Dora (b) (4) (b) (4)	15 Sep 2020 00:02:47

US3012073
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	15 Sep 2020 00:03:11

US3012073
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	15 Sep 2020 00:03:11

FDA-CBER-2022-1614-0000937

US3012073
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:51:23

US3012073
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 04:01:56
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct as entered' (Site from System).	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:51:27
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Sep 2020 15:51:23
User entered '23 Sep 2020'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:51:23

FDA-CBER-2022-1614-0000939

US3012073
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:51:23

US3012073
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:51:23

US3012073
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:51:33

US3012073
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	23 Sep 2020 15:51:33

FDA-CBER-2022-1614-0000943

US3012073
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Michelle Listz (b) (4) (b) (4)	29 Sep 2020 16:25:50

FDA-CBER-2022-1614-0000944

US3012073
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '25 Sep 2020'	Michelle Listz (b) (4) (b) (4)	29 Sep 2020 16:25:50

FDA-CBER-2022-1614-0000945

US3012073
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Contact Made (CONTACT MADE)'	Michelle Listz (b) (4) (b) (4)	29 Sep 2020 16:25:50

FDA-CBER-2022-1614-0000946

US3012073
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Michelle Listz (b) (4) (b) (4)	29 Sep 2020 16:25:50

US3012073
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Michelle Listz (b) (4) (b) (4)	29 Sep 2020 16:26:13

FDA-CBER-2022-1614-0000948

US3012073
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	29 Sep 2020 16:26:13

FDA-CBER-2022-1614-0000949

US3012073
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:58:24

FDA-CBER-2022-1614-0000950

US3012073
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '1 Oct 2020'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:58:24

FDA-CBER-2022-1614-0000951

US3012073
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Clinic (Clinic)'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:58:24

FDA-CBER-2022-1614-0000952

US3012073
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'VISIT3'	System	01 Oct 2020 22:58:24

FDA-CBER-2022-1614-0000953

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000954

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '1 Oct 2020'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000955

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '10:55'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000956

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '1 Oct 2020 10:55'	System	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000957

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '98.4' F	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000958

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Oral (Oral)'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000959

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000960

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '69'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000961

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'bpm'	System	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000962

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '12'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000963

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'breaths/min'	System	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000964

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '112'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000965

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000966

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '71'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000967

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered 'mmHg'	System	01 Oct 2020 22:59:07

FDA-CBER-2022-1614-0000968

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05

FDA-CBER-2022-1614-0000969

US3012073
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05

FDA-CBER-2022-1614-0000970

US3012073
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:27

FDA-CBER-2022-1614-0000971

US3012073
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered empty.	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:27

FDA-CBER-2022-1614-0000972

US3012073
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:52

FDA-CBER-2022-1614-0000973

US3012073
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '1 Oct 2020'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:52

FDA-CBER-2022-1614-0000974

US3012073
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered '11:03'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:52

US3012073
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '1 Oct 2020 11:03'	System	01 Oct 2020 22:59:52

FDA-CBER-2022-1614-0000976

US3012073
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:08:02
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	01 Oct 2020 22:59:58

FDA-CBER-2022-1614-0000977

US3012073
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User entered '1'	System	01 Oct 2020 22:59:58

FDA-CBER-2022-1614-0000978

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 64'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000979

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-10-08T21:40:19', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '74c90be2-ac72-4791-a32e-15a8c63db98c'	System	09 Oct 2020 02:40:40
User entered 'No (N)'	System	09 Oct 2020 02:40:40

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-10-08T21:40:26', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '74c90be2-ac72-4791-a32e-15a8c63db98c'	System	09 Oct 2020 02:40:40
User entered 'No (N)'	System	09 Oct 2020 02:40:40

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-10-08T21:40:34', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '74c90be2-ac72-4791-a32e-15a8c63db98c'	System	09 Oct 2020 02:40:40
User entered '08 Oct 2020 21:40:34'	System	09 Oct 2020 02:40:40

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '06 Oct 2020 00:01'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000983

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '10 Oct 2020 23:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000984

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 71'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000985

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-10-13T00:13:50', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd2bac172-0108-4ef0-8646-39e6a89d6e43'	System	13 Oct 2020 05:14:13
User entered 'No (N)'	System	13 Oct 2020 05:14:13

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-10-13T00:14:05', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd2bac172-0108-4ef0-8646-39e6a89d6e43'	System	13 Oct 2020 05:14:13
User entered 'No (N)'	System	13 Oct 2020 05:14:13

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-10-13T00:14:09', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd2bac172-0108-4ef0-8646-39e6a89d6e43'	System	13 Oct 2020 05:14:13
User entered '13 Oct 2020 00:14:09'	System	13 Oct 2020 05:14:13

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '13 Oct 2020 00:01'	System	07 Aug 2020 01:11:01

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '17 Oct 2020 23:59'	System	07 Aug 2020 01:11:01

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 78'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000991

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-10-21T11:13:26', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '78e78add-6a65-463c-b3bb-36171361d454'	System	21 Oct 2020 16:14:05
User entered 'No (N)'	System	21 Oct 2020 16:14:05

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-10-21T11:13:30', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '78e78add-6a65-463c-b3bb-36171361d454'	System	21 Oct 2020 16:14:05
User entered 'No (N)'	System	21 Oct 2020 16:14:05

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-10-21T11:14:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '78e78add-6a65-463c-b3bb-36171361d454'	System	21 Oct 2020 16:14:05
User entered '21 Oct 2020 11:14:00'	System	21 Oct 2020 16:14:05

FDA-CBER-2022-1614-0000994

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '20 Oct 2020 00:01'	System	07 Aug 2020 01:11:01

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '24 Oct 2020 23:59'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000996

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 92'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0000997

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-11-06T18:39:03', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'bf006340-7f33-4e12-b83c-cc54241c8f3d'	System	07 Nov 2020 00:39:23
User entered 'No (N)'	System	07 Nov 2020 00:39:23

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-11-06T18:39:15', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'bf006340-7f33-4e12-b83c-cc54241c8f3d'	System	07 Nov 2020 00:39:23
User entered 'No (N)'	System	07 Nov 2020 00:39:23

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-11-06T18:39:20', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'bf006340-7f33-4e12-b83c-cc54241c8f3d'	System	07 Nov 2020 00:39:23
User entered '06 Nov 2020 18:39:20'	System	07 Nov 2020 00:39:23

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '03 Nov 2020 00:01'	System	07 Aug 2020 01:11:01

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '07 Nov 2020 23:59'	System	07 Aug 2020 01:11:01

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 99'	System	07 Aug 2020 01:11:01

FDA-CBER-2022-1614-0001003

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-11-14T11:57:14', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '6bb0ed94-242c-4234-ab27-22e9b47d26b0'	System	14 Nov 2020 17:57:28
User entered 'No (N)'	System	14 Nov 2020 17:57:28

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-11-14T11:57:20', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '6bb0ed94-242c-4234-ab27-22e9b47d26b0'	System	14 Nov 2020 17:57:28
User entered 'No (N)'	System	14 Nov 2020 17:57:28

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-11-14T11:57:25', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '6bb0ed94-242c-4234-ab27-22e9b47d26b0'	System	14 Nov 2020 17:57:28
User entered '14 Nov 2020 11:57:25'	System	14 Nov 2020 17:57:28

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '10 Nov 2020 00:01'	System	07 Aug 2020 01:11:01

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:21
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '14 Nov 2020 23:59'	System	07 Aug 2020 01:11:01

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46
Data entry locked.	System	07 Aug 2020 01:11:01
User entered 'Day 106'	System	07 Aug 2020 01:11:01

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001016

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001019

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001034

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '17 Nov 2020 00:01'	System	07 Aug 2020 01:11:01

US3012073
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:22:46
Data entry locked.	System	07 Aug 2020 01:11:01
User entered '21 Nov 2020 23:59'	System	07 Aug 2020 01:11:01

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001037

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-11-25T07:31:23', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'f549ae25-d06d-44b8-bc6c-f7e471e10b3e'	System	25 Nov 2020 13:31:38
User entered 'No (N)'	System	25 Nov 2020 13:31:38

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-11-25T07:31:28', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'f549ae25-d06d-44b8-bc6c-f7e471e10b3e'	System	25 Nov 2020 13:31:38
User entered 'No (N)'	System	25 Nov 2020 13:31:38

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-11-25T07:31:35', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'f549ae25-d06d-44b8-bc6c-f7e471e10b3e'	System	25 Nov 2020 13:31:38
User entered '25 Nov 2020 07:31:35'	System	25 Nov 2020 13:31:38

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001041

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001042

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001043

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-02T14:16:14', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '20a4e756-5142-4766-820e-7a365b1b6a8c'	System	02 Dec 2020 20:16:30
User entered 'No (N)'	System	02 Dec 2020 20:16:30

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-02T14:16:17', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '20a4e756-5142-4766-820e-7a365b1b6a8c'	System	02 Dec 2020 20:16:30
User entered 'No (N)'	System	02 Dec 2020 20:16:30

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-02T14:16:25', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '20a4e756-5142-4766-820e-7a365b1b6a8c'	System	02 Dec 2020 20:16:30
User entered '02 Dec 2020 14:16:25'	System	02 Dec 2020 20:16:30

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001047

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001049

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001054

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001055

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001056

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001057

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001058

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001059

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001060

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001061

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001062

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001063

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001064

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001066

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001069

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001070

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001074

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001075

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001076

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001077

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-15T09:32:47', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '52be21a8-04ff-4a90-ba79-afeb85facc9c'	System	15 Dec 2020 15:33:02
User entered 'No (N)'	System	15 Dec 2020 15:33:02

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-15T09:32:52', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '52be21a8-04ff-4a90-ba79-afeb85facc9c'	System	15 Dec 2020 15:33:02
User entered 'No (N)'	System	15 Dec 2020 15:33:02

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-15T09:32:58', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '52be21a8-04ff-4a90-ba79-afeb85facc9c'	System	15 Dec 2020 15:33:02
User entered '15 Dec 2020 09:32:58'	System	15 Dec 2020 15:33:02

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001081

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001082

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001083

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-20T11:48:51', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c9144512-1d73-475c-92d2-5d893b7194da'	System	20 Dec 2020 17:49:03
User entered 'No (N)'	System	20 Dec 2020 17:49:03

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-20T11:48:55', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c9144512-1d73-475c-92d2-5d893b7194da'	System	20 Dec 2020 17:49:03
User entered 'No (N)'	System	20 Dec 2020 17:49:03

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-20T11:49:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'c9144512-1d73-475c-92d2-5d893b7194da'	System	20 Dec 2020 17:49:03
User entered '20 Dec 2020 11:49:00'	System	20 Dec 2020 17:49:03

FDA-CBER-2022-1614-0001086

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001087

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001088

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001089

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-29T10:50:35', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '2546958b-029d-49fc-bc45-1320c8b37810'	System	29 Dec 2020 16:50:57
User entered 'No (N)'	System	29 Dec 2020 16:50:57

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-29T10:50:48', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '2546958b-029d-49fc-bc45-1320c8b37810'	System	29 Dec 2020 16:50:57
User entered 'No (N)'	System	29 Dec 2020 16:50:57

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2020-12-29T10:50:54', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '2546958b-029d-49fc-bc45-1320c8b37810'	System	29 Dec 2020 16:50:57
User entered '29 Dec 2020 10:50:54'	System	29 Dec 2020 16:50:57

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001095

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-03T10:54:55', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd8bc77bb-8c7a-4f97-be13-79a44cb55c7d'	System	03 Jan 2021 16:55:07
User entered 'No (N)'	System	03 Jan 2021 16:55:07

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-03T10:55:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd8bc77bb-8c7a-4f97-be13-79a44cb55c7d'	System	03 Jan 2021 16:55:07
User entered 'No (N)'	System	03 Jan 2021 16:55:07

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-03T10:55:04', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'd8bc77bb-8c7a-4f97-be13-79a44cb55c7d'	System	03 Jan 2021 16:55:07
User entered '03 Jan 2021 10:55:04'	System	03 Jan 2021 16:55:07

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001101

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-13T10:38:27', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '44421896-7d3a-463d-9b2c-223bd7c472bf'	System	13 Jan 2021 16:38:40
User entered 'No (N)'	System	13 Jan 2021 16:38:40

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-13T10:38:32', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '44421896-7d3a-463d-9b2c-223bd7c472bf'	System	13 Jan 2021 16:38:40
User entered 'No (N)'	System	13 Jan 2021 16:38:40

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-13T10:38:36', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '44421896-7d3a-463d-9b2c-223bd7c472bf'	System	13 Jan 2021 16:38:40
User entered '13 Jan 2021 10:38:36'	System	13 Jan 2021 16:38:40

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:22:46

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-16T10:51:37', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '704a3ab4-b068-4661-99ad-bff446cdcc9c'	System	16 Jan 2021 16:52:01
User entered 'No (N)'	System	16 Jan 2021 16:52:01

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-16T10:51:42', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '704a3ab4-b068-4661-99ad-bff446cdcc9c'	System	16 Jan 2021 16:52:01
User entered 'No (N)'	System	16 Jan 2021 16:52:01

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-16T10:51:58', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '704a3ab4-b068-4661-99ad-bff446cdcc9c'	System	16 Jan 2021 16:52:01
User entered '16 Jan 2021 10:51:58'	System	16 Jan 2021 16:52:01

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001113

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-23T18:24:16', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '40d543df-70a8-4b8b-a199-c7c0e0b4a72a'	System	24 Jan 2021 00:24:26
User entered 'No (N)'	System	24 Jan 2021 00:24:26

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-23T18:24:19', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '40d543df-70a8-4b8b-a199-c7c0e0b4a72a'	System	24 Jan 2021 00:24:26
User entered 'No (N)'	System	24 Jan 2021 00:24:26

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-01-23T18:24:23', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '40d543df-70a8-4b8b-a199-c7c0e0b4a72a'	System	24 Jan 2021 00:24:26
User entered '23 Jan 2021 18:24:23'	System	24 Jan 2021 00:24:26

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001119

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-01T16:09:30', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'fff41216-b64a-4db7-8efb-a59aae352791'	System	01 Feb 2021 22:09:41
User entered 'No (N)'	System	01 Feb 2021 22:09:41

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-01T16:09:33', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'fff41216-b64a-4db7-8efb-a59aae352791'	System	01 Feb 2021 22:09:41
User entered 'No (N)'	System	01 Feb 2021 22:09:41

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-01T16:09:38', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'fff41216-b64a-4db7-8efb-a59aae352791'	System	01 Feb 2021 22:09:41
User entered '01 Feb 2021 16:09:38'	System	01 Feb 2021 22:09:41

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:22:46

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-08T11:11:58', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '0f2816eb-8ebc-4968-8c1f-8234379c0db8'	System	08 Feb 2021 17:15:46
User entered 'No (N)'	System	08 Feb 2021 17:15:46

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-08T11:12:01', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '0f2816eb-8ebc-4968-8c1f-8234379c0db8'	System	08 Feb 2021 17:15:46
User entered 'No (N)'	System	08 Feb 2021 17:15:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-08T11:12:15', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '0f2816eb-8ebc-4968-8c1f-8234379c0db8'	System	08 Feb 2021 17:15:46
User entered '08 Feb 2021 11:12:15'	System	08 Feb 2021 17:15:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001130

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001131

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-13T19:23:56', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'b2f953d0-fb06-418a-bf24-ba600deb5c2d'	System	14 Feb 2021 01:24:20
User entered 'No (N)'	System	14 Feb 2021 01:24:20

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-13T19:23:59', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'b2f953d0-fb06-418a-bf24-ba600deb5c2d'	System	14 Feb 2021 01:24:20
User entered 'No (N)'	System	14 Feb 2021 01:24:20

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-13T19:24:04', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'b2f953d0-fb06-418a-bf24-ba600deb5c2d'	System	14 Feb 2021 01:24:20
User entered '13 Feb 2021 19:24:04'	System	14 Feb 2021 01:24:20

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001137

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-20T00:01:47', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '33706f3a-1a7e-4fd5-ac86-78eb36be3bbd'	System	20 Feb 2021 06:02:46
User entered 'No (N)'	System	20 Feb 2021 06:02:46

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-20T00:01:50', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '33706f3a-1a7e-4fd5-ac86-78eb36be3bbd'	System	20 Feb 2021 06:02:46
User entered 'No (N)'	System	20 Feb 2021 06:02:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-20T00:02:02', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '33706f3a-1a7e-4fd5-ac86-78eb36be3bbd'	System	20 Feb 2021 06:02:46
User entered '20 Feb 2021 00:02:02'	System	20 Feb 2021 06:02:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:22:46

FDA-CBER-2022-1614-0001143

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-28T14:06:29-06:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'dceb8a71-7696-4040-adba-207aa32a9beb'	System	28 Feb 2021 20:06:53
User entered 'No (N)'	System	28 Feb 2021 20:06:53

US3012073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-28T14:06:40-06:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'dceb8a71-7696-4040-adba-207aa32a9beb'	System	28 Feb 2021 20:06:53
User entered 'No (N)'	System	28 Feb 2021 20:06:53

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-28T14:06:48-06:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: 'dceb8a71-7696-4040-adba-207aa32a9beb'	System	28 Feb 2021 20:06:53
User entered '28 Feb 2021 14:06:48'	System	28 Feb 2021 20:06:53

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:22:46

US3012073
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:52:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:22:46
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:22:46

US3012073

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:52:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-28T14:07:02-06:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '384c265a-152a-4a71-b982-f6d9b972dca5'	System	28 Feb 2021 20:07:23
User entered 'No (N)'	System	28 Feb 2021 20:07:23

US3012073
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 09 Jun 2021 14:52:36
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (638923dea085f623)', Time: '2021-02-28T14:07:21-06:00', User OID: 'PatientReportedOutcome (US3012073)', ODM File OID: '384c265a-152a-4a71-b982-f6d9b972dca5'	System	28 Feb 2021 20:07:23
User entered '28 Feb 2021 14:07:21'	System	28 Feb 2021 20:07:23

US3012073
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:23:28
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	30 Oct 2020 14:30:18

US3012073
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:23:28
User entered '29 Oct 2020'	Pamela Fidler (b) (4)	30 Oct 2020 14:30:18

US3012073
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:23:28
User entered 'Contact Made (CONTACT MADE)'	Pamela Fidler (b) (4)	30 Oct 2020 14:30:18

FDA-CBER-2022-1614-0001153

US3012073
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:23:28
User entered empty.	Pamela Fidler (b) (4)	30 Oct 2020 14:30:18

US3012073
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:23:28
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	30 Oct 2020 14:30:23

US3012073
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	30 Oct 2020 14:30:23

FDA-CBER-2022-1614-0001156

US3012073
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 21:27:38

US3012073
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '02 Dec 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 21:27:38

US3012073
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Contact Made (CONTACT MADE)'	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 21:27:38

US3012073
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 21:27:38

US3012073
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 21:27:41

FDA-CBER-2022-1614-0001161

US3012073
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	02 Dec 2020 21:27:41

FDA-CBER-2022-1614-0001162

US3012073
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jessica Ruff (b) (4) (b) (4)	29 Dec 2020 23:33:09

US3012073
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '29 Dec 2020'	Jessica Ruff (b) (4) (b) (4)	29 Dec 2020 23:33:09

US3012073
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Contact Made (CONTACT MADE)'	Jessica Ruff (b) (4) (b) (4)	29 Dec 2020 23:33:09

US3012073
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jessica Ruff (b) (4) (b) (4)	29 Dec 2020 23:33:09

US3012073
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jessica Ruff (b) (4) (b) (4)	29 Dec 2020 23:33:12

US3012073
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	29 Dec 2020 23:33:12

US3012073
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	03 Feb 2021 00:42:16

US3012073
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '02 Feb 2021'	Pamela Fidler (b) (4)	03 Feb 2021 00:42:16

FDA-CBER-2022-1614-0001170

US3012073
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Contact Made (CONTACT MADE)'	Pamela Fidler (b) (4)	03 Feb 2021 00:42:16

US3012073
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Pamela Fidler (b) (4)	03 Feb 2021 00:42:16

US3012073
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	03 Feb 2021 00:42:19

US3012073
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	03 Feb 2021 00:42:19

FDA-CBER-2022-1614-0001174

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:00:08

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '11 Jan 2021'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:00:08

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Clinic (Clinic)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:00:08

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 00:00:08

FDA-CBER-2022-1614-0001178

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:52:36
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '11 Jan 2021'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:00:41

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:52:36
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	09 Apr 2021 20:38:23
User entered '0'	Pamela Fidler (b) (4)	08 Apr 2021 16:22:29
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:14:43

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:52:36
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:00:41

US3012073

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:52:36

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 02:07:03
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	09 Apr 2021 20:38:23
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	08 Apr 2021 16:23:41
User entered 'Amendment 6 or later (Amendment 6 or later)'	Pamela Fidler (b) (4)	08 Apr 2021 16:22:29
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:11:11
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:14:43

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:52:36
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '11 Jan 2021'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:00:41

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:52:36
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Placebo (Placebo)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:00:41

FDA-CBER-2022-1614-0001184

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:52:36
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:23:24
User entered 'Placebo (Placebo)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:00:41

FDA-CBER-2022-1614-0001185

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:52:36
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 01:23:24
User entered 'Placebo (Placebo)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:00:41

FDA-CBER-2022-1614-0001186

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:52:36
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:00:41

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:52:36
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	12 Jan 2021 00:00:41

FDA-CBER-2022-1614-0001188

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:52:36
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	12 Jan 2021 00:00:41

FDA-CBER-2022-1614-0001189

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '66.5' in	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '131.8' lb	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '20.99820'	System	12 Jan 2021 00:29:24
DataPoint set to visible.	System	12 Jan 2021 00:00:41

FDA-CBER-2022-1614-0001192

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '66.5' in	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '131.8' lb	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '20.99820'	System	12 Jan 2021 00:29:24
DataPoint set to visible.	System	12 Jan 2021 00:00:41

FDA-CBER-2022-1614-0001195

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User accepted default value 'Pre-Dose (PREDOSE)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001196

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '11 Jan 2021'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '15:42'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '11 Jan 2021 15:42'	System	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001200

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '98.1' F	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001201

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Oral (Oral)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '84'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001204

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'bpm'	System	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '14'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001206

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'breaths/min'	System	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001207

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '141'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'mmHg'	System	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001209

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '92'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001210

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'mmHg'	System	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001211

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '66.5' in	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '131.8' lb	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:52:36
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '20.99820'	System	12 Jan 2021 00:29:24
DataPoint set to visible.	System	12 Jan 2021 00:00:41

FDA-CBER-2022-1614-0001214

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User accepted default value 'Post-Dose (POSTDOSE)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001215

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)' reason for change: Data Entry Error	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:51
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty; reason for change Data Entry Error	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:51
User entered '11 Jan 2021'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Jan 2021 00:29:51
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001218

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001219

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Jan 2021 00:29:51
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001220

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Jan 2021 00:29:51
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001223

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001224

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Jan 2021 00:29:51
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001226

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Jan 2021 00:29:51
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001227

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	12 Jan 2021 00:29:24

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Jan 2021 00:29:51
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Jan 2021 00:29:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001229

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	12 Jan 2021 00:29:24

FDA-CBER-2022-1614-0001230

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:30:13

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '11 Jan 2021'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:30:13

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:32:42

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:32:42

US3012073

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:32:42

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'mRNA-1273'	System	12 Jan 2021 00:32:42
DataPoint set to visible.	System	12 Jan 2021 00:00:41

FDA-CBER-2022-1614-0001236

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '11 Jan 2021'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:32:42

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '17:33'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:32:42

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '11 Jan 2021 17:33'	System	12 Jan 2021 00:32:42

FDA-CBER-2022-1614-0001239

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Left Arm (LEFT ARM)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:32:42

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'ONCE'	System	12 Jan 2021 00:32:42

FDA-CBER-2022-1614-0001241

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 00:32:42

FDA-CBER-2022-1614-0001242

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:01:12

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '11 Jan 2021'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:01:12

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '17:07'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:01:12

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '11 Jan 2021 17:07'	System	12 Jan 2021 00:01:12

FDA-CBER-2022-1614-0001246

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 14:52:36
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:01:53

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 14:52:36
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '11 Jan 2021'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:01:53

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 14:52:36
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '16:05'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:01:53

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 14:52:36
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '11 Jan 2021 16:05'	System	12 Jan 2021 00:01:53

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 00:02:00

US3012073
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	12 Jan 2021 00:02:00

FDA-CBER-2022-1614-0001252

US3012073
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 00:37:39

US3012073
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:37:39

US3012073
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:37:39

US3012073
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:34:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 00:37:39

US3012073
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:37:44

US3012073
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	20 Jan 2021 00:37:44

FDA-CBER-2022-1614-0001258

US3012073
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	20 Jan 2021 00:37:44
DataPoint set to visible.	System	20 Jan 2021 00:37:44

FDA-CBER-2022-1614-0001259

US3012073
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:20:37

FDA-CBER-2022-1614-0001260

US3012073
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '08 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:20:37

US3012073
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:20:37

US3012073
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'OLD29'	System	09 Feb 2021 00:20:37

FDA-CBER-2022-1614-0001263

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001264

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001265

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '08 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:03

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '16:09'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001267

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '08 Feb 2021 16:09'	System	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001268

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '97.7' F	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001269

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001270

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001271

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '89'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001272

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'bpm'	System	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001273

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:03

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'breaths/min'	System	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001275

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '130'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001276

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'mmHg'	System	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001277

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '86'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001278

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'mmHg'	System	09 Feb 2021 00:21:03

FDA-CBER-2022-1614-0001279

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001280

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001281

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '08 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:24

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '17:18'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001283

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '08 Feb 2021 17:18'	System	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001284

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '98.8' F	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:24

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:24

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001287

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '71'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001288

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'bpm'	System	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001289

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001290

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'breaths/min'	System	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001291

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '130'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001292

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'mmHg'	System	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001293

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '82'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001294

US3012073
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'mmHg'	System	09 Feb 2021 00:21:24

FDA-CBER-2022-1614-0001295

US3012073
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:36

US3012073
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '08 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:36

US3012073
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:56

US3012073
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:56

US3012073
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:56

US3012073
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'mRNA-1273'	System	09 Feb 2021 00:21:56
DataPoint set to visible.	System	20 Jan 2021 00:37:44

US3012073
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '08 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:56

US3012073
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '16:47'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:56

US3012073
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '08 Feb 2021 16:47'	System	09 Feb 2021 00:21:56

FDA-CBER-2022-1614-0001304

US3012073
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:56

US3012073
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'ONCE'	System	09 Feb 2021 00:21:56

FDA-CBER-2022-1614-0001306

US3012073
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:52:36
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 00:21:56

FDA-CBER-2022-1614-0001307

US3012073
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Feb 2021 00:21:59

US3012073
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	09 Feb 2021 00:21:59

FDA-CBER-2022-1614-0001309

US3012073
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 00:43:30

US3012073
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User closed query 'Per GCL Lab Recon: Immuno: Sample dated 05 MAR 2021 is recorded under OL-D57 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:07:55
Query 'Per GCL Lab Recon: Immuno: Sample dated 05 MAR 2021 is recorded under OL-D57 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Thank you.' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	24 Mar 2021 21:56:37
User opened query 'Per GCL Lab Recon: Immuno: Sample dated 05 MAR 2021 is recorded under OL-D57 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:43:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	03 Mar 2021 05:50:09
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'This was due to inclement weather' (Site from System).	Pamela Fidler (b) (4)	02 Mar 2021 21:42:39
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Feb 2021 00:43:30
User entered '24 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 00:43:30

US3012073
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 00:43:30

US3012073
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:52:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 00:43:30

US3012073
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 00:43:35

US3012073
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:52:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	25 Feb 2021 00:43:35

US3012073
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	24 Mar 2021 21:54:33

US3012073
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered '05 Mar 2021'	Pamela Fidler (b) (4)	24 Mar 2021 21:54:33

US3012073
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered 'Clinic (Clinic)'	Pamela Fidler (b) (4)	24 Mar 2021 21:54:33

US3012073
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:52:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'OLD57'	System	24 Mar 2021 21:54:33

FDA-CBER-2022-1614-0001319

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	24 Mar 2021 21:54:59

FDA-CBER-2022-1614-0001320

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered '05 Mar 2021'	Pamela Fidler (b) (4)	24 Mar 2021 21:54:59

FDA-CBER-2022-1614-0001321

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered '16:00'	Pamela Fidler (b) (4)	24 Mar 2021 21:54:59

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '05 Mar 2021 16:00'	System	24 Mar 2021 21:54:59

FDA-CBER-2022-1614-0001323

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered '97.7' F	Pamela Fidler (b) (4)	24 Mar 2021 21:54:59

FDA-CBER-2022-1614-0001324

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered 'Oral (Oral)'	Pamela Fidler (b) (4)	24 Mar 2021 21:54:59

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered empty.	Pamela Fidler (b) (4)	24 Mar 2021 21:54:59

FDA-CBER-2022-1614-0001326

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered '112'	Pamela Fidler (b) (4)	24 Mar 2021 21:54:59

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'bpm'	System	24 Mar 2021 21:54:59

FDA-CBER-2022-1614-0001328

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered '14'	Pamela Fidler (b) (4)	24 Mar 2021 21:54:59

FDA-CBER-2022-1614-0001329

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'breaths/min'	System	24 Mar 2021 21:54:59

FDA-CBER-2022-1614-0001330

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered '112'	Pamela Fidler (b) (4)	24 Mar 2021 21:54:59

FDA-CBER-2022-1614-0001331

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'mmHg'	System	24 Mar 2021 21:54:59

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered '81'	Pamela Fidler (b) (4)	24 Mar 2021 21:54:59

FDA-CBER-2022-1614-0001333

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered 'mmHg'	System	24 Mar 2021 21:54:59

FDA-CBER-2022-1614-0001334

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001335

US3012073
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:52:36
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52

FDA-CBER-2022-1614-0001336

US3012073
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	24 Mar 2021 21:55:07

US3012073
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:52:36
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	24 Mar 2021 21:55:22
User entered '05 Mar 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	24 Mar 2021 21:55:22
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	24 Mar 2021 21:55:07
User entered empty.	Pamela Fidler (b) (4)	24 Mar 2021 21:55:07

US3012073
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	24 Mar 2021 21:55:33

US3012073
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered '05 Mar 2021'	Pamela Fidler (b) (4)	24 Mar 2021 21:55:33

FDA-CBER-2022-1614-0001340

US3012073
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:47:02
User entered '16:48'	Pamela Fidler (b) (4)	24 Mar 2021 21:55:33

US3012073
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:52:36
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '05 Mar 2021 16:48'	System	24 Mar 2021 21:55:33

FDA-CBER-2022-1614-0001342

US3012073
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 14:52:36
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User closed query 'Per source, MAAE of ALS is recorded with the start date of Un/Oct/2020. Please verify and update EDC AE log accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:55:59
Query 'Per source, MAAE of ALS is recorded with the start date of Un/Oct/2020. Please verify and update EDC AE log accordingly.' answered with 'Per CCGs, AEs are recorded once in EDC and severity is updated, as applicable. All severities are recorded separately on source.' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	14 Apr 2021 21:19:20
User opened query 'Per source, MAAE of ALS is recorded with the start date of Un/Oct/2020. Please verify and update EDC AE log accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:27:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:20:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)' reason for change: New Information	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:23:26
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:51

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:20:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:28:20
User entered 'USA-US006-2021-mRNA-1273-P301000006'	System	08 Mar 2021 16:28:12
User entered 'New'	(b) (4), (b) (6)	08 Mar 2021 16:28:12

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.		14 Apr 2021 16:20:53
User closed query 'IQVIA Medical query: Please provide the date that the subject was diagnosed with amyotrophic lateral sclerosis' (Site from Safety).		31 Mar 2021 14:02:32
Query 'IQVIA Medical query: Please provide the date that the subject was diagnosed with amyotrophic lateral sclerosis' answered with 'Date of diagnosis recorded as UN/OCT/2020. An exact date has not been obtained.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	30 Mar 2021 15:55:06
User opened query 'IQVIA Medical query: Please provide the date that the subject was diagnosed with amyotrophic lateral sclerosis' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 23:58:44
User closed query 'PV Query: The reported event is a worsening of amyotrophic lateral sclerosis. PV Query: Did the subject have a medical history of ALS? If YES, please add to the Medical History page of the eCRF.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:25:11
Query 'PV Query: The reported event is a worsening of amyotrophic lateral sclerosis. PV Query: Did the subject have a medical history of ALS? If YES, please add to the Medical History page of the eCRF.' answered with 'ALS was diagnosed post entry into the study. This condition was first entered as an AE and then worsened and the AE term was updated, per CCGs ' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 12:57:59
User opened query 'PV Query: The reported event is a worsening of amyotrophic lateral sclerosis. PV Query: Did the subject have a medical history of ALS? If YES, please add to the Medical History page of the eCRF.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:31:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
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)	09 Mar 2021 18:56:41

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Adverse event

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:56:41
User closed query 'For coding purposes, for term WORSENING OF ALS, please spell out the abbreviation ALS.' (Site from Coder).	(b) (4), (b) (6)	06 Mar 2021 18:40:46
Query 'For coding purposes, for term WORSENING OF ALS, please spell out the abbreviation ALS.' answered with 'updated' (Site from Coder).	Pamela Fidler (b) (4)	06 Mar 2021 16:30:17
Data point term sent to Coder	System	06 Mar 2021 16:30:16
Coding entries removed.	Pamela Fidler (b) (4)	06 Mar 2021 16:30:10
User entered 'WORSENING OF amyotrophic lateral sclerosis' reason for change: Data Entry Error	Pamela Fidler (b) (4)	06 Mar 2021 16:30:10
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)	06 Mar 2021 13:58:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 13:58:00
User opened query 'For coding purposes, for term WORSENING OF ALS, please spell out the abbreviation ALS.' (Site from Coder).	(b) (4), (b) (6)	06 Mar 2021 13:56:37
Data point term sent to Coder	System	05 Mar 2021 23:46:34
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:46:32
User entered 'WORSENING OF ALS' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:46:32
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)	12 Jan 2021 16:51:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 16:51:56
Data point term sent to Coder	System	12 Jan 2021 16:50:39
User entered 'ALS'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:21:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:21:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:21:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:21:26
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '26 Feb 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:46:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Jan 2021 16:46:46
User entered '01 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Jan 2021 16:46:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Jan 2021 16:49:53
User entered 'UN Oct 2020' (non-conformant).	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:21:28
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	12 Jan 2021 16:49:53

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US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:24:48
Query 'Per source, AE ended 22Mar2021. Please verify and update EDC accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:24:46
User opened query 'Per source, AE ended 22Mar2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:22:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:05
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:25:17
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'No end date will be provided as subject withdrew from study and no further follow-up will occur.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 12:58:24
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:32:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:07
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	12 Jan 2021 16:49:53

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US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:34:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	05 Mar 2021 23:35:16
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:35:16
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	05 Mar 2021 23:34:52
User entered 'No (N)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '0'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

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US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '0'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

FDA-CBER-2022-1614-0001360

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:25
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '1' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:34:52
User entered '0'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:29
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 12:57:26
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Records requested x4 but still not received. No further attemps to retrieve records will be made.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	01 Apr 2021 12:56:37
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 23:56:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '26 Feb 2021' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:34:52
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:34
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 12:57:07
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Records requested x4 but still not received. No further attemps to retrieve records will be made.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	01 Apr 2021 13:04:51
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 23:57:34
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:25:26

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Pending discharge paperwork. Once requested 3 times, site will not request again and no further updates will be provided' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 12:59:32
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:33:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '02 Mar 2021' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:34:52
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:23:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:34:52
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:23:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

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US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '1' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:34:52
User entered '0'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:23:28
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '0'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:23:30
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '0'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

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US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:23:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Not Related (NOT RELATED)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:23:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Not Related (NOT RELATED)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:23:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Not Applicable (NOT APPLICABLE)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:23:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	05 Mar 2021 23:35:28
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:35:28
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	05 Mar 2021 23:34:52
User entered '1'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:23:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '1' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:34:52
User entered '0'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 16:35:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:27:13
User closed query 'Per source, Other Action Taken, has ConProcedure recorded. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 14:27:12
Query 'Per source, Other Action Taken, has ConProcedure recorded. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	14 Apr 2021 21:18:05
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	14 Apr 2021 21:18:00
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	14 Apr 2021 21:18:00
User opened query 'Per source, Other Action Taken, has ConProcedure recorded. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:24:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:25:30
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Pending. ' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 12:59:40

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Concomitant Procedure

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:32:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '0'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:24:54
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:25:43
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Will not be updated as subject withdrew from study' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 12:59:52
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:31:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:24:55
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:24:57
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 12:56:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Records requested x4 but still not received. No further attemps to retrieve records will be made.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	01 Apr 2021 13:05:06
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 23:57:05
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:25:36
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Pending' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 12:59:57

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:32:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Mar 2021 23:36:47
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Mar 2021 23:36:47
User entered 'Pt was admitted to hospital due to dehydration and malnutrition, as a result of worsening ALS' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:36:47
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Mar 2021 23:35:16
User entered empty.	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	05 Mar 2021 23:35:16
User entered '0'	System	12 Jan 2021 16:49:53

US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	12 Jan 2021 16:49:53

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US3012073
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:52:36
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '0'	System	05 Mar 2021 23:34:52

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US3012073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:52:36

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User closed query 'Per SAE Medical Records, several ConMeds are reported during hospitalization, but not captured in source/EDC. Please review and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:57:26
Query 'Per SAE Medical Records, several ConMeds are reported during hospitalization, but not captured in source/EDC. Please review and update EDC accordingly.' answered with 'ConMeds entered and updated on source' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:55:05
User opened query 'Per SAE Medical Records, several ConMeds are reported during hospitalization, but not captured in source/EDC. Please review and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:36:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:27:31
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:26:57

US3012073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 18:24:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 18:24:23
Data point term sent to Coder	System	07 Aug 2020 01:28:28
User entered 'Testosterone'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

FDA-CBER-2022-1614-0001386

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Hormone Replacement'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

FDA-CBER-2022-1614-0001387

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 13:23:58
Query 'Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Unknown' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	18 Sep 2020 12:05:40
User opened query 'Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 10:57:02
User entered '0.5'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'mL (mL)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

FDA-CBER-2022-1614-0001389

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:30
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'every week (QS)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

FDA-CBER-2022-1614-0001394

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:58:37
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Current and ongoing. Per protocol, must be reported.' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:28:10
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 01:27:45
User entered '1 Jan 2015'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)' reason for change: New Information	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 14:20:33
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '1 Jan 2021' reason for change: New Information	Dean Skiles (b) (4) (b) (4)	12 Jan 2021 14:20:33
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	07 Aug 2020 01:27:45

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	07 Aug 2020 01:27:45

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US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	07 Aug 2020 01:27:45

FDA-CBER-2022-1614-0001401

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '803 (803)'	System	07 Aug 2020 01:27:45

FDA-CBER-2022-1614-0001402

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 14:31:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 14:31:53
Data point term sent to Coder	System	30 Oct 2020 14:31:22
User entered 'Influenza Vaccine'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

FDA-CBER-2022-1614-0001404

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Influenza Prevention'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:56
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '.7'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

FDA-CBER-2022-1614-0001406

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:58
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'mL (mL)'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:00
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

FDA-CBER-2022-1614-0001408

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 22:33:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:30
User closed query 'Per source, frequency is recorded as, Once. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:56:28
Query 'Per source, frequency is recorded as, Once. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 19:42:18
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 19:42:01
User entered 'once (ONCE)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 19:42:01
User opened query 'Per source, frequency is recorded as, Once. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:22:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'once daily (QD)'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:26
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Intramuscular (INTRAMUSCULAR)'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

FDA-CBER-2022-1614-0001411

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:28
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

FDA-CBER-2022-1614-0001412

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:30
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '29 Oct 2020'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '0'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

FDA-CBER-2022-1614-0001414

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '29 Oct 2020'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Pamela Fidler (b) (4)	30 Oct 2020 14:31:17

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	16 Apr 2021 19:42:01
User entered '1'	System	30 Oct 2020 14:31:17

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	16 Apr 2021 19:42:01
User entered '1'	System	30 Oct 2020 14:31:17

FDA-CBER-2022-1614-0001419

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	16 Apr 2021 19:42:01
User entered '804 (804)'	System	30 Oct 2020 14:31:17

FDA-CBER-2022-1614-0001420

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:59
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 14:33:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 14:33:57
Data point term sent to Coder	System	30 Oct 2020 14:32:23
User entered 'Pneumococcal Vaccine'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

FDA-CBER-2022-1614-0001421

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

FDA-CBER-2022-1614-0001422

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:04
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Pneumonia Prevention'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

FDA-CBER-2022-1614-0001423

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:06
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '.5'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

FDA-CBER-2022-1614-0001424

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'mL (mL)'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

FDA-CBER-2022-1614-0001426

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 22:33:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:36
User closed query 'Per source, ConMed Frequency is recorded as, Once. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:56:34
Query 'Per source, ConMed Frequency is recorded as, Once. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 19:44:24
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 19:44:10
User entered 'once (ONCE)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 19:44:10
User opened query 'Per source, ConMed Frequency is recorded as, Once. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:23:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'once daily (QD)'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

FDA-CBER-2022-1614-0001427

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Intramuscular (INTRAMUSCULAR)'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '29 Oct 2020'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

FDA-CBER-2022-1614-0001431

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '0'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:55
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '29 Oct 2020'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Pamela Fidler (b) (4)	30 Oct 2020 14:32:04

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	16 Apr 2021 19:44:10
User entered '1'	System	30 Oct 2020 14:32:04

FDA-CBER-2022-1614-0001436

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	16 Apr 2021 19:44:10
User entered '1'	System	30 Oct 2020 14:32:04

FDA-CBER-2022-1614-0001437

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	16 Apr 2021 19:44:10
User entered '804 (804)'	System	30 Oct 2020 14:32:04

US3012073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:27:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: GLYCOPYRRONIUM, PRODUCTSYNONYM: GLYCOPYRROLATE [GLYCOPYRRONIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:48:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:48:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
Data point term sent to Coder	System	05 Mar 2021 23:39:29
User entered 'Gycopyrolate'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'excess saliva, due to worsening of ALS'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'UN'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Other (OTHER)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'UNKNOWN'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.		14 Apr 2021 16:33:19
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

FDA-CBER-2022-1614-0001447

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '05 Mar 2021'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:26
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:28
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:33:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:38:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	05 Mar 2021 23:38:58

FDA-CBER-2022-1614-0001454

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	05 Mar 2021 23:38:58

FDA-CBER-2022-1614-0001455

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	05 Mar 2021 23:38:58

FDA-CBER-2022-1614-0001456

US3012073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:34:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:16:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:16:42
Data point term sent to Coder	System	05 Mar 2021 23:39:29
User entered 'Tramadol'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:34:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:34:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Pain, due to worsening of ALS'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:34:59
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'UN'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:35:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Other (OTHER)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:35:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'UNKNOWN'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:35:04
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:35:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:35:07
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '05 Mar 2021'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:35:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:35:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:35:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:35:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:39:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	05 Mar 2021 23:39:27

FDA-CBER-2022-1614-0001472

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	05 Mar 2021 23:39:27

FDA-CBER-2022-1614-0001473

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	05 Mar 2021 23:39:27

FDA-CBER-2022-1614-0001474

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:15
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 20:47:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 20:47:01
Data point term sent to Coder	System	15 Apr 2021 20:46:31
User entered 'Acetaminophen'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

FDA-CBER-2022-1614-0001475

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'worsening of ALS (AE #1)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '650'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:25
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:30
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:36
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '26 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.		16 Apr 2021 19:24:42
DataPoint Un-verified.		16 Apr 2021 19:24:40
DataPoint Verified.		16 Apr 2021 19:24:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 22:33:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:51:44
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:49:23
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:49:23
User entered '02 Mar 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:49:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	15 Apr 2021 20:47:24
User entered '28 Feb 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:47:24
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	15 Apr 2021 20:46:16
User entered '28 Mar 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:46:16
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:44:07
DataPoint inactivated with code reason code Data not required.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:40:52

US3012073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE IN WATER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:29:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:29:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
Data point term sent to Coder	System	15 Apr 2021 20:48:34
User entered 'Dextrose/Water'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:55
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

FDA-CBER-2022-1614-0001494

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'worsening of ALS (AE #1)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

FDA-CBER-2022-1614-0001495

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:06
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '25'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'mL (mL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:15
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '26 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:25
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 20:48:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 20:48:27
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:27
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 20:48:13
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 22:33:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:50:39
User entered '02 Mar 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:49:34
User closed query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:38:20
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 19:54:46
User entered '28 Feb 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 19:54:46
Query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' answered with 'Corrected' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 19:48:50
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 19:45:22
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 19:45:22
User entered '28 Mar 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 19:45:22
User opened query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:33:00
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:27:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '28 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:27:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:48:13

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:48:13

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US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:48:13

FDA-CBER-2022-1614-0001509

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:48:13

FDA-CBER-2022-1614-0001510

US3012073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:52:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:19:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:19:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:31
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
Data point term sent to Coder	System	15 Apr 2021 20:49:35
User entered 'Sodium Chloride 0.9%'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

FDA-CBER-2022-1614-0001512

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'worsening of ALS (AE #1)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '1000'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'mL (mL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:55
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'other (OTHER)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:00
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'continous'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

FDA-CBER-2022-1614-0001518

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:04
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:07
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '26 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:10
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '26 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:49:25

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:49:25

FDA-CBER-2022-1614-0001526

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:49:25

FDA-CBER-2022-1614-0001527

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:49:25

FDA-CBER-2022-1614-0001528

US3012073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:52:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: MAALOX [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:16:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:16:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
Data point term sent to Coder	System	15 Apr 2021 20:51:36
User entered 'Maalox'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:26
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:28
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'worsening of ALS (AE #1)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

FDA-CBER-2022-1614-0001531

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:30
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '30'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'mL (mL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

FDA-CBER-2022-1614-0001533

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

FDA-CBER-2022-1614-0001534

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:30:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

FDA-CBER-2022-1614-0001537

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:30:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:30:42
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '26 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:30:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 22:33:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:50:58
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:49:47
User entered '02 Mar 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:49:47
Query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:38:28
User opened query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:34:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '28 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:03

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:51:03

FDA-CBER-2022-1614-0001544

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:51:03

FDA-CBER-2022-1614-0001545

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:51:03

FDA-CBER-2022-1614-0001546

US3012073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:52:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:54:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:54:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
Data point term sent to Coder	System	15 Apr 2021 20:52:38
User entered 'Docusate Sodium'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

FDA-CBER-2022-1614-0001548

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'worsening of ALS (AE #1)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

FDA-CBER-2022-1614-0001549

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '100'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

FDA-CBER-2022-1614-0001552

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'twice daily (BID)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '26 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:25
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 22:33:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:51:05
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:49:58
User entered '02 Mar 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:49:58
Query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:38:33
User opened query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:35:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '28 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '2'	System	15 Apr 2021 20:51:42

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	15 Apr 2021 20:51:42

FDA-CBER-2022-1614-0001563

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '804 (804)'	System	15 Apr 2021 20:51:42

FDA-CBER-2022-1614-0001564

US3012073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:52:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM HYDROXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:49:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:49:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:47
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
Data point term sent to Coder	System	15 Apr 2021 20:53:39
User entered 'Magnesium Hydroxide'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'worsening of ALS (AE #1)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:28
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '30'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'mL (mL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:42
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'other (OTHER)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:46
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Q6H'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:47
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

FDA-CBER-2022-1614-0001573

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

FDA-CBER-2022-1614-0001574

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '26 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:56
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 22:33:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:51:10
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:50:11
User entered '02 Mar 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:50:11
Query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:38:39
User opened query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:37:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '28 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:52:58

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:52:58

FDA-CBER-2022-1614-0001580

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:52:58

FDA-CBER-2022-1614-0001581

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:52:58

FDA-CBER-2022-1614-0001582

US3012073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:52:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 08:34:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 08:34:58
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
Data point term sent to Coder	System	15 Apr 2021 20:53:40
User entered 'Ondasetron'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'worsening of ALS (AE #1)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

FDA-CBER-2022-1614-0001585

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '4'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

FDA-CBER-2022-1614-0001586

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:15
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

FDA-CBER-2022-1614-0001587

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

FDA-CBER-2022-1614-0001591

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:25
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '26 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 22:33:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:51:16
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:50:19
User entered '02 Mar 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:50:19
Query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:38:43
User opened query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:37:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '28 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:53:27

FDA-CBER-2022-1614-0001598

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:53:27

FDA-CBER-2022-1614-0001599

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:53:27

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:46
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: GUAIFENESIN/DEXTROMETHORPHAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 20:56:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 20:56:01
Data point term sent to Coder	System	15 Apr 2021 20:54:41
User entered 'Guaifenesin/Dextromethorphan'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

FDA-CBER-2022-1614-0001601

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'worsening of ALS (AE #1)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

FDA-CBER-2022-1614-0001603

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '10'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:56
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'mL (mL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:59
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:04
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	15 Apr 2021 20:54:55
User entered 'other (OTHER)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:55
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	15 Apr 2021 20:54:07
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Q4H'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:10
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

FDA-CBER-2022-1614-0001609

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '26 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 22:33:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:51:22
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:50:27
User entered '02 Mar 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:50:27
Query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:38:50
User opened query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:38:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '28 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:38:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:54:55
User entered '1'	System	15 Apr 2021 20:54:07

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:54:55
User entered '1'	System	15 Apr 2021 20:54:07

FDA-CBER-2022-1614-0001617

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered empty.	System	15 Apr 2021 20:54:55
User entered '804 (804)'	System	15 Apr 2021 20:54:07

FDA-CBER-2022-1614-0001618

US3012073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:52:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:24:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:24:56
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
Data point term sent to Coder	System	15 Apr 2021 20:54:41
User entered 'Melatonin'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:31
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

FDA-CBER-2022-1614-0001620

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'worsening of ALS (AE #1)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

FDA-CBER-2022-1614-0001621

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '6'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '26 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 22:33:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:51:27
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:50:35
User entered '02 Mar 2021' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Apr 2021 20:50:35
Query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:39:00
User opened query 'Per source, end date is recorded as, 28Mar2021. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:39:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:00
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '28 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:07
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:54:37

US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	15 Apr 2021 20:54:37

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US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '1'	System	15 Apr 2021 20:54:37

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US3012073
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:52:36
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '804 (804)'	System	15 Apr 2021 20:54:37

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US3012073
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 14:52:36
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 18:17:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:58:20
User closed query 'Per source, Feeding Tube is listed as a ConProcedure. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:57:49
Query 'Per source, Feeding Tube is listed as a ConProcedure. Please verify and update EDC accordingly.' answered with 'ConProcedure entered' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:12:20
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:09:59
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:09:59
User opened query 'Per source, Feeding Tube is listed as a ConProcedure. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:35:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	03 Sep 2020 21:27:42

US3012073
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:52:36
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered '26 Feb 2021'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:10:34

US3012073
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:52:36
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Feeding Tube'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:10:34

US3012073
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:52:36
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:10:34

US3012073
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:52:36
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 21:32:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	15 Apr 2021 20:10:34

FDA-CBER-2022-1614-0001641

US3012073
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:52:36
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered '05 Mar 2021'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:41:22

FDA-CBER-2022-1614-0001642

US3012073
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:52:36
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'SAE (specify) (SAE)'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:41:22

FDA-CBER-2022-1614-0001643

US3012073

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:52:36

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)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:49:05
User closed query 'Per CDM re-query: Per response please enter only the #' symbol and 'AE logline number' for example #1 and remove all the remaining details.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:51:55
Query 'Per CDM re-query: Per response please enter only the #' symbol and 'AE logline number' for example #1 and remove all the remaining details.' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	26 Mar 2021 14:24:58
User entered '#1' reason for change: Data Entry Error	Pamela Fidler (b) (4)	26 Mar 2021 14:24:46
User opened query 'Per CDM re-query: Per response please enter only the #' symbol and 'AE logline number' for example #1 and remove all the remaining details.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 02:23:57
User closed query 'Per CDM: Per sponsor review, if reason for study discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 02:23:57
Query 'Per CDM: Per sponsor review, if reason for study discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' answered with '.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 13:00:26
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 13:00:22
User entered 'WORSENING OF ALS (AE #1)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	15 Mar 2021 13:00:22

US3012073

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:52:36

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM: Per sponsor review, if reason for study discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 16:05:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'Worsening of ALS'	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:41:22

US3012073
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:52:36
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:41:22

FDA-CBER-2022-1614-0001646

US3012073
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:52:36
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:41:22

US3012073
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:52:36
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:41:22

FDA-CBER-2022-1614-0001648

US3012073
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:52:36
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	05 Mar 2021 23:41:22

FDA-CBER-2022-1614-0001649

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:23
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:02:54
Un-reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:02:51
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'USA-US006-2021-MRNA-1273-P301000006'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001650

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:24
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Yes (Y)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001651

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001652

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001653

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Yes (Y)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001654

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Yes (Y)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001655

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001656

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001657

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Laurence'	System	08 Mar 2021 16:28:12

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Chu'	System	08 Mar 2021 16:28:12

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered '3100 Red River Street'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001660

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Austin'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001661

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'TX'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001662

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered '78705'	System	08 Mar 2021 16:28:12

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:02:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'US'	System	08 Mar 2021 16:28:49

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '2'	System	15 Apr 2021 14:05:38
User entered '1'	System	08 Mar 2021 16:28:49

FDA-CBER-2022-1614-0001665

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:23
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:02:54
Un-reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:02:51
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'USA-US006-2021-MRNA-1273-P301000006'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001666

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:24
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Yes (Y)'	System	08 Mar 2021 16:28:12

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001669

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Yes (Y)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001670

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Yes (Y)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001671

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001672

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001673

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Laurence'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001674

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Chu'	System	08 Mar 2021 16:28:12

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered '3100 Red River Street'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001676

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Austin'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001677

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'TX'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001678

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered '78705'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001679

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:02:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'US'	System	08 Mar 2021 16:28:49

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '2'	System	15 Apr 2021 14:05:38
User entered '1'	System	08 Mar 2021 16:28:49

FDA-CBER-2022-1614-0001681

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 14:52:36
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
User entered '08/Mar/2021 11:28'	(b) (4) System	08 Mar 2021 16:28:49

FDA-CBER-2022-1614-0001682

US3012073

Folder: SAE USA-US006-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:52:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:02:54
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:49

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:23
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:02:54
Un-reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:02:51
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'USA-US006-2021-MRNA-1273-P301000006'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001684

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:24
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Yes (Y)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001685

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001686

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001687

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Yes (Y)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001688

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Yes (Y)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001689

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001690

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'No (N)'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001691

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Laurence'	System	08 Mar 2021 16:28:12

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Chu'	System	08 Mar 2021 16:28:12

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered '3100 Red River Street'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001694

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'Austin'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001695

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered 'TX'	System	08 Mar 2021 16:28:12

FDA-CBER-2022-1614-0001696

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:28:42
User entered '78705'	System	08 Mar 2021 16:28:12

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:25:29
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:02:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:24
User entered 'US'	System	08 Mar 2021 16:28:49

FDA-CBER-2022-1614-0001698

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 14:52:36
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
User entered '2'	System	15 Apr 2021 14:05:38
User entered '1'	System	08 Mar 2021 16:28:49

FDA-CBER-2022-1614-0001699

US3012073
Folder: SAE USA-US006-2021-MRNA-1273-P301000006
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 14:52:36
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:13:58
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:02
User entered '15/Apr/2021 10:05'	(b) (4) System	15 Apr 2021 14:05:38

US3012073

Folder: SAE USA-US006-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:52:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:33:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 01:13:58
User signature succeeded.	Laurence Chu (b) (4)	15 Apr 2021 16:35:02
User entered '1'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:05:38