US3202036 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:40:20

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US3202036
Form: Participant Creation
Data signed: (b) (4) **09 Apr 2021 13:17:41**
Generated On: 09 Jun 2021 15:40:20

Participant ID	US3202036

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0428104

US3202036
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428105

US3202036
Folder: Screening
Form: Demographics
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
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	False
If race is Other, specify	
Unknown	False
Not reported	True

FDA-CBER-2022-1614-0428106

US3202036
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Date of Informed Consent *(dd MMM yyyy)*	6 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-2022-1614-0428107

US3202036
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

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US3202036
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Were any significant conditions reported?	Yes ■ No ☐

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US3202036
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3202036
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

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US3202036
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Condition	HYPERLIPEDEMA
Start date (dd MMM yyyy)	UN MAR 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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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US3202036
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1986
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1986
Stop Year (derived)	1986

FDA-CBER-2022-1614-0428113

US3202036
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Condition	TOTAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1986
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1986
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 1986
Stop Year (derived)	1986

FDA-CBER-2022-1614-0428114

US3202036
Folder: Screening
Form: Medical History (12)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Condition	TYPE 2 DIABETES MELLITUS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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US3202036
Folder: Screening
Form: Medical History (14)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Condition	NEUROPATHY CAUSED BY BACK SURGERY
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0428116

US3202036
Folder: Screening
Form: Medical History (15)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0428117

US3202036
Folder: Screening
Form: Medical History (19)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1961
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☑
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1961
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1961
Start Year (derived)	1961
Stop Month and Year (derived)	JAN 1961
Stop Year (derived)	1961

FDA-CBER-2022-1614-0428118

US3202036
Folder: Screening
Form: Medical History (21)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428119

US3202036
Folder: Screening
Form: Medical History (22)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Condition	INCARCERATED RECURRENT INCISIONAL VENTRAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0428120

US3202036
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	6 AUG 2020
Time of assessment *(00:00-23:59)*	12:30 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 12:30
Height *(xxx.x)*	160.7 cm
Weight *(xxx.x)*	83.0 kg
BMI *(xxx.x)*	32.14003 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)	

US3202036
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 01:48:14**
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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.

FDA-CBER-2022-1614-0428122

US3202036
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **13 Feb 2021 01:48:14**
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Date of assessment *(dd MMM yyyy)*	6 AUG 2020
Is the participant of childbearing potential?	Yes ☐ No ■
If No, what is the reason?	Surgically sterile ■ Post-menopausal ☐ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	UN UNK 1986
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

US3202036
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3202036
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	6 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

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US3202036
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

What was the date of randomization? *(dd MMM yyyy)*	06 AUG 2020
What was the participant's randomization number?	184969
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 ■

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US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Height	ND - Not Done
Weight	ND - Not Done

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US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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)*	6 AUG 2020
Time of assessment *(00:00-23:59)*	12:30 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 12:30
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0428129

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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)*	6 AUG 2020
Time of assessment *(00:00-23:59)*	13:53 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 13:53
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0428130

US3202036
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428131

US3202036
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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)*	6 AUG 2020
What was the treatment time? *(00:00-23:59)*	13:03 (24 HR)
Treatment Date and Time (derived)	6 AUG 2020 13:03
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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US3202036
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	6 AUG 2020
Collection time *(00:00-23:59)*	12:38 (24 HR)
Collection date and time (derived)	6 AUG 2020 12:38

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Collection date *(dd MMM yyyy)*			6 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:36	6 AUG 2020 12:36
Nasopharyngeal Swab 2	No		

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US3202036
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

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US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °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	06 AUG 2020 13:52
PC Open Date & Time	06 AUG 2020 13:23
PC Close Date & Time	06 AUG 2020 15:53

FDA-CBER-2022-1614-0428136

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 AUG 2020 17:42
PC Open Date & Time	06 AUG 2020 16:48
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-0428137

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.3 °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	07 AUG 2020 17:52
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

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US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 AUG 2020 17:20
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 AUG 2020 18:42
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	10 AUG 2020 17:28
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-0428141

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20

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**	97.5 °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	11 AUG 2020 19:02
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	12 AUG 2020 18:19
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0428143

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20

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 13:53
PC Open Date & Time	06 AUG 2020 13:23
PC Close Date & Time	06 AUG 2020 15:53

FDA-CBER-2022-1614-0428144

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20

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	06 AUG 2020 17:43
PC Open Date & Time	06 AUG 2020 16:48
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-0428145

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20

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 17:53
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-0428146

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20

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	08 AUG 2020 17:20
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20

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 18:43
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20

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 17:28
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20

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	11 AUG 2020 19:02
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-0428150

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20

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 18:20
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

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

FDA-CBER-2022-1614-0428152

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	06 AUG 2020 13:54
PC Open Date & Time	06 AUG 2020 13:23
PC Close Date & Time	06 AUG 2020 15:53

FDA-CBER-2022-1614-0428153

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-2022-1614-0428154

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	06 AUG 2020 17:45
PC Open Date & Time	06 AUG 2020 16:48
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-0428155

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428156

	Yes ☐
PC Time stamp	07 AUG 2020 17:54
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428158

	Yes ☐
PC Time stamp	08 AUG 2020 17:21
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428160

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20

	Yes ☐
PC Time stamp	09 AUG 2020 18:43
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

FDA-CBER-2022-1614-0428161

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428162

	Yes ☐
PC Time stamp	10 AUG 2020 17:29
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428164

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428165

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428166

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20

	Yes ☐
PC Time stamp	12 AUG 2020 18:20
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0428167

US3202036
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 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-2022-1614-0428168

US3202036
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428169

US3202036
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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*	

FDA-CBER-2022-1614-0428170

US3202036
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428171

US3202036
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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	ATTEMPTS X3 LVM

If Contact Not Made, please provide Comments

FDA-CBER-2022-1614-0428172

US3202036
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428173

US3202036
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT2

FDA-CBER-2022-1614-0428174

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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)*	12:57 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 12:57
Temperature *(xxx.x)*	36.1 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	58 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	79 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0428175

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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)*	15:03 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 15:03
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0428176

US3202036
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428177

US3202036
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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)*	13:50 (24 HR)
Treatment Date and Time (derived)	3 SEP 2020 13:50
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-2022-1614-0428178

US3202036
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	3 SEP 2020
Collection time *(00:00-23:59)*	13:25 (24 HR)
Collection date and time (derived)	3 SEP 2020 13:25

FDA-CBER-2022-1614-0428179

US3202036
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Collection date *(dd MMM yyyy)*			3 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:11	3 SEP 2020 13:11
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0428180

US3202036
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428181

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °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	03 SEP 2020 15:04
PC Open Date & Time	03 SEP 2020 14:10
PC Close Date & Time	03 SEP 2020 16:40

FDA-CBER-2022-1614-0428182

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	03 SEP 2020 21:33
PC Open Date & Time	03 SEP 2020 17:35
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-0428183

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20

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**	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	04 SEP 2020 21:57
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-0428184

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20

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**	97.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 SEP 2020 19:40
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 SEP 2020 18:01
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20

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**	97.0 °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 SEP 2020 19:16
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 SEP 2020 12:47
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °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 SEP 2020 12:20
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20

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 15:04
PC Open Date & Time	03 SEP 2020 14:10
PC Close Date & Time	03 SEP 2020 16:40

FDA-CBER-2022-1614-0428190

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20

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 21:34
PC Open Date & Time	03 SEP 2020 17:35
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-0428191

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20

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 21:58
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-0428192

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20

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 19:41
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20

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	06 SEP 2020 18:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20

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 19:16
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20

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 12:47
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20

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 12:21
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 ☐

FDA-CBER-2022-1614-0428198

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	03 SEP 2020 15:05
PC Open Date & Time	03 SEP 2020 14:10
PC Close Date & Time	03 SEP 2020 16:40

FDA-CBER-2022-1614-0428199

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-2022-1614-0428200

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	03 SEP 2020 21:34
PC Open Date & Time	03 SEP 2020 17:35
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-0428201

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428202

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428203

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428204

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20

	Yes ☐
PC Time stamp	05 SEP 2020 19:41
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-0428205

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428206

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20

	Yes ☐
PC Time stamp	06 SEP 2020 18:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-0428207

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428208

	Yes ☐
PC Time stamp	07 SEP 2020 19:17
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-0428209

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428210

	Yes ☐
PC Time stamp	08 SEP 2020 12:48
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-0428211

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428212

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428213

US3202036
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0428214

US3202036
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428215

US3202036
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 SEP 2020
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments *If Contact Not Made, please provide Comments*	SUBJECT DID NOT RETURN CALL

FDA-CBER-2022-1614-0428216

US3202036
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428217

US3202036
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0428218

US3202036
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428219

US3202036
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-0428220

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	01 OCT 2020
Time of assessment *(00:00-23:59)*	12:14 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 12:14
Temperature *(xxx.x)*	36.3 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0428221

US3202036
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428222

US3202036
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	01 OCT 2020
Collection time *(00:00-23:59)*	12:30 (24 HR)
Collection date and time (derived)	01 OCT 2020 12:30

US3202036
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 01:48:14**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428224

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

FDA-CBER-2022-1614-0428226

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

FDA-CBER-2022-1614-0428228

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

FDA-CBER-2022-1614-0428230

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	04 NOV 2020 10:20:15
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

FDA-CBER-2022-1614-0428231

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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 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):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	10 NOV 2020 11:50:16
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

FDA-CBER-2022-1614-0428232

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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 ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 08:46:50
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

FDA-CBER-2022-1614-0428233

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	22 NOV 2020 14:06:38
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

FDA-CBER-2022-1614-0428234

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	28 NOV 2020 15:11:35
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

FDA-CBER-2022-1614-0428235

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 09:09:53
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	14 DEC 2020 12:01:56
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

FDA-CBER-2022-1614-0428237

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	28 DEC 2020 18:01:24
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	02 JAN 2021 23:02:42
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

FDA-CBER-2022-1614-0428241

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	10 JAN 2021 18:12:23
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

FDA-CBER-2022-1614-0428242

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	20 JAN 2021 11:45:22
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

FDA-CBER-2022-1614-0428243

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 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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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 11:24:25
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

FDA-CBER-2022-1614-0428246

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	06 FEB 2021 14:34:35
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

FDA-CBER-2022-1614-0428247

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	15 FEB 2021 10:19:41
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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 02:01:37
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

FDA-CBER-2022-1614-0428249

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	01 MAR 2021 12:01:34
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

FDA-CBER-2022-1614-0428250

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 215
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 MAR 2021 11:16:38
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

FDA-CBER-2022-1614-0428251

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 222
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 MAR 2021 01:39:06
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

FDA-CBER-2022-1614-0428252

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 MAR 2021 10:48:01
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

FDA-CBER-2022-1614-0428253

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 236
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	31 MAR 2021 13:39:25
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

FDA-CBER-2022-1614-0428254

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 APR 2021 21:16:44
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

FDA-CBER-2022-1614-0428255

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 250
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	10 APR 2021 00:13:58
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

FDA-CBER-2022-1614-0428256

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 257
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	17 APR 2021 00:24:14
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

FDA-CBER-2022-1614-0428257

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428258

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	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

FDA-CBER-2022-1614-0428259

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 271
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 MAY 2021 00:50:07
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

FDA-CBER-2022-1614-0428260

TIMEPOINT	DAY 278
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	08 MAY 2021 00:01
Patient Cloud Close Date & Time	12 MAY 2021 23:59

FDA-CBER-2022-1614-0428262

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428263

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

FDA-CBER-2022-1614-0428264

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	22 MAY 2021 00:01
Patient Cloud Close Date & Time	26 MAY 2021 23:59

TIMEPOINT	DAY 299
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	29 MAY 2021 00:01
Patient Cloud Close Date & Time	02 JUN 2021 23:59

FDA-CBER-2022-1614-0428268

TIMEPOINT	DAY 306
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

FDA-CBER-2022-1614-0428270

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428273

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	19 JUN 2021 00:01
Patient Cloud Close Date & Time	23 JUN 2021 23:59

FDA-CBER-2022-1614-0428274

TIMEPOINT	DAY 327
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	26 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

FDA-CBER-2022-1614-0428276

TIMEPOINT	DAY 334
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

FDA-CBER-2022-1614-0428278

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428279

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428283

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

TIMEPOINT	DAY 362
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	31 JUL 2021 00:01
Patient Cloud Close Date & Time	04 AUG 2021 23:59

FDA-CBER-2022-1614-0428286

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428287

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	07 AUG 2021 00:01
Patient Cloud Close Date & Time	11 AUG 2021 23:59

FDA-CBER-2022-1614-0428288

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

FDA-CBER-2022-1614-0428292

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428293

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	28 AUG 2021 00:01
Patient Cloud Close Date & Time	01 SEP 2021 23:59

FDA-CBER-2022-1614-0428294

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	04 SEP 2021 00:01
Patient Cloud Close Date & Time	08 SEP 2021 23:59

FDA-CBER-2022-1614-0428296

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

FDA-CBER-2022-1614-0428298

TIMEPOINT	DAY 411
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 425
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	02 OCT 2021 00:01
Patient Cloud Close Date & Time	06 OCT 2021 23:59

FDA-CBER-2022-1614-0428304

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 439
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

FDA-CBER-2022-1614-0428308

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428309

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	23 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

FDA-CBER-2022-1614-0428310

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 OCT 2021 00:01
Patient Cloud Close Date & Time	03 NOV 2021 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428313

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 NOV 2021 00:01
Patient Cloud Close Date & Time	10 NOV 2021 23:59

FDA-CBER-2022-1614-0428314

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

FDA-CBER-2022-1614-0428316

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

TIMEPOINT	DAY 481
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	27 NOV 2021 00:01
Patient Cloud Close Date & Time	01 DEC 2021 23:59

FDA-CBER-2022-1614-0428320

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

TIMEPOINT	DAY 502
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428329

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	01 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428331

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	08 JAN 2022 00:01
Patient Cloud Close Date & Time	12 JAN 2022 23:59

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428333

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	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

TIMEPOINT	DAY 537
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	22 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

FDA-CBER-2022-1614-0428338

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

FDA-CBER-2022-1614-0428342

TIMEPOINT	DAY 565
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	19 FEB 2022 00:01
Patient Cloud Close Date & Time	23 FEB 2022 23:59

FDA-CBER-2022-1614-0428344

TIMEPOINT	DAY 572
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	26 FEB 2022 00:01
Patient Cloud Close Date & Time	02 MAR 2022 23:59

FDA-CBER-2022-1614-0428346

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 MAR 2022 00:01
Patient Cloud Close Date & Time	09 MAR 2022 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428349

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	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428351

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	19 MAR 2022 00:01
Patient Cloud Close Date & Time	23 MAR 2022 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 MAR 2022 00:01
Patient Cloud Close Date & Time	30 MAR 2022 23:59

TIMEPOINT	DAY 607
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	02 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

FDA-CBER-2022-1614-0428356

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 APR 2022 00:01
Patient Cloud Close Date & Time	13 APR 2022 23:59

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

TIMEPOINT	DAY 635
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 APR 2022 00:01
Patient Cloud Close Date & Time	04 MAY 2022 23:59

FDA-CBER-2022-1614-0428364

TIMEPOINT	DAY 642
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	07 MAY 2022 00:01
Patient Cloud Close Date & Time	11 MAY 2022 23:59

FDA-CBER-2022-1614-0428366

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 MAY 2022 00:01
Patient Cloud Close Date & Time	18 MAY 2022 23:59

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2022 00:01
Patient Cloud Close Date & Time	25 MAY 2022 23:59

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 MAY 2022 00:01
Patient Cloud Close Date & Time	01 JUN 2022 23:59

FDA-CBER-2022-1614-0428372

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428373

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	04 JUN 2022 00:01
Patient Cloud Close Date & Time	08 JUN 2022 23:59

FDA-CBER-2022-1614-0428374

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

TIMEPOINT	DAY 691
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

TIMEPOINT	DAY 698
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	02 JUL 2022 00:01
Patient Cloud Close Date & Time	06 JUL 2022 23:59

FDA-CBER-2022-1614-0428382

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 705
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2022 00:01
Patient Cloud Close Date & Time	13 JUL 2022 23:59

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 JUL 2022 00:01
Patient Cloud Close Date & Time	03 AUG 2022 23:59

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 AUG 2022 00:01
Patient Cloud Close Date & Time	10 AUG 2022 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428393

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	13 AUG 2022 00:01
Patient Cloud Close Date & Time	17 AUG 2022 23:59

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2022 00:01
Patient Cloud Close Date & Time	21 SEP 2022 23:59

TIMEPOINT	DAY 782
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	24 SEP 2022 00:01
Patient Cloud Close Date & Time	28 SEP 2022 23:59

FDA-CBER-2022-1614-0428406

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0428407

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	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

TIMEPOINT	DAY 796
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 ☐

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3202036
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 09 Jun 2021 15:40:20

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		01 MAR 2021 12:02:12

FDA-CBER-2022-1614-0428411

US3202036
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **26 Mar 2021 12:37:04**
Generated On: 09 Jun 2021 15:40:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0428412

US3202036
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **26 Mar 2021 12:37:04**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428413

US3202036
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0428414

US3202036
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428415

US3202036
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	4 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0428416

US3202036
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428417

US3202036
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	1 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0428418

US3202036
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428419

US3202036
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT4

FDA-CBER-2022-1614-0428420

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428421

US3202036
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

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-2022-1614-0428422

US3202036
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	3 MAR 2021
Collection time *(00:00-23:59)*	08:42 (24 HR)
Collection date and time (derived)	3 MAR 2021 08:42

FDA-CBER-2022-1614-0428423

US3202036
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428424

US3202036
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	1 APR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0428425

US3202036
Folder: Safety Call Day 239 (1)
Form: Continuing
Data signed: (b) (4) **09 Apr 2021 13:17:46**
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428426

US3202036
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20

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

FDA-CBER-2022-1614-0428427

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

US3202036
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:40:20

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

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Generate Next COVID-19 Assessment	Yes ☐ No ☐

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **09 Apr 2021 13:17:45**
Generated On: 09 Jun 2021 15:40:20

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	1 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-0428431

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **22 Apr 2021 17:52:37**
Generated On: 09 Jun 2021 15:40:20

Date of updated informed consent *(dd MMM yyyy)*	1 FEB 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)*	1 FEB 2021
Participant randomization assignment	mRNA-1273 ■ Placebo ☐
Actual Dose 1	mRNA-1273 ■ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ■ Placebo ☐ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ■
Placebo Only Flag	
Continuing with mRNA-1273	

FDA-CBER-2022-1614-0428432

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **09 Apr 2021 13:17:45**
Generated On: 09 Jun 2021 15:40:20

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	1 FEB 2021
Collection time *(00:00-23:59)*	12:46 (24 HR)
Collection date and time (derived)	1 FEB 2021 12:46

FDA-CBER-2022-1614-0428433

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **09 Apr 2021 13:17:45**
Generated On: 09 Jun 2021 15:40:20

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	1 FEB 2021
Collection time *(00:00 - 23:59)*	12:43
Collection Date and Time (derived)	1 FEB 2021 12:43

US3202036
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **19 Mar 2021 13:01:35**
Generated On: 09 Jun 2021 15:40:20

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

If Yes, enter details on the Adverse Events form.

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US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **15 Mar 2021 12:11:32**
Generated On: 09 Jun 2021 15:40:20

AEID	USA-US128-2021-MRNA-1273-P301000007
Adverse event	WORSENING OF INCARCERATED RECURRENT INCISIONAL VENTRAL HERNIA
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)*	09 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	12 JAN 2021
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)*	10 JAN 2021
Hospital Discharge Date *(dd MMM yyyy)*	15 JAN 2021
Admitted to ICU?	Yes ☐ No ■

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

	SUBJECT CONTACTED SITE REPORTING RECURRENCE OF VENTRAL HERNIA HAD OCCURRED AND WAS OBSTRUCTING SMALL BOWEL. SHE WAS SCHEDULED TENTATIVELY FOR SURGICAL CORRECTION ON 12/JAN/2021. HOSPITAL ADMISSION RECORDS RECEIVED BUT WILL REQUEST UPDATED RECORDS ON 13JAN2021 FOR SURGICAL RECORD AND INFORMATION ON DISCHARGE WHEN SUBJECT IS D/C'D UPDATE: MEDICAL RECORDS OF SURGERY RECEIVED INDICATE VENTRAL HERNIA REPAIR SURGERY PERFORMED SUCCESSFULLY ON 12JAN2021 BUT NO D/C DATE OR D/C SUMMARY INCLUDED ON RECORDS RECEIVED TO DATE. THESE RECORDS STATE THAT THIS HAS BEEN A RECURRENT ISSUE FOR 4 YEARS, BUT HAD BEEN STABLE W/O SYMPTOMS FOR LONG WHILE PRIOR TO THIS EPISODE. MEDICAL HISTORY UPDATED TO REFLECT THE CONDITION WAS PRESENT AT SCREENING AND AE TERM UPDATED PER MR.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **15 Mar 2021 12:11:32**
Generated On: 09 Jun 2021 15:40:20

AEID	
Adverse event	DIARRHEA
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)*	28 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)*	1 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **15 Mar 2021 12:11:32**
Generated On: 09 Jun 2021 15:40:20

AEID	
Adverse event	VOMITING
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)*	28 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)*	1 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **09 Apr 2021 13:17:45**
Generated On: 09 Jun 2021 15:40:20

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

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

Name of Medication	TRULICITY
Prophylaxis	Yes ☐ No ■
Indication	TYPE 2 DIABETES MELLITUS
Dose per administration	1.5
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)*	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ■
	804 ☐

Name of Medication	TIZANIDINE
Prophylaxis	Yes ☐ No ■
Indication	BACK PAIN
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)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes ☐ No ■
Indication	GERD
Dose per administration	40
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	10 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 ■

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ■
Indication	SENSORY NEUROPATHY
Dose per administration	400
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ■ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	10 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

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

Name of Medication	CALCIUM
Prophylaxis	Yes ■ No ☐
Indication	VITAMIN SUPPLEMENT
Dose per administration	600
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
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 ■

Name of Medication	RAW B COMPLEX
Prophylaxis	Yes ■ No ☐
Indication	VITAMIN SUPPLEMENT
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ■ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	CRANBERRY SUPPLEMENT
Prophylaxis	Yes ■ No ☐
Indication	TO PREVENT UTIS
Dose per administration	4200
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **09 Apr 2021 13:17:41**
Generated On: 09 Jun 2021 15:40:20

Name of Medication	COQ10
Prophylaxis	Yes ■ No ☐
Indication	VITAMIN SUPPLEMENT
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)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

Name of Medication	VITAMIN D3
Prophylaxis	Yes ■ No ☐
Indication	VITAMIN SUPPLEMENT
Dose per administration	125
Dose unit	mg ☐ ug ■ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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

Name of Medication	VITAMIN E
Prophylaxis	Yes ■ No ☐
Indication	VITAMIN SUPPLEMENT
Dose per administration	180
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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

Name of Medication	FLUTICASONE SPRAY
Prophylaxis	Yes ☐ No ■
Indication	SEASONAL ALLERGIES
Dose per administration	50
Dose unit	mg ☐ ug ■ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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

Name of Medication	HYDROMORPHONE
Prophylaxis	Yes ☐ No ■
Indication	INCARCERATED VENTRAL HERNIA
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)*	10 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	10 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

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Folder: Concomitant Medication and Vaccination (1)
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Name of Medication	GENERAL ANESTHESIA (NOT OTHERWISE SPECIFIED)
Prophylaxis	Yes ☐ No ■
Indication	INCARCERATED RECURRENT INCISIONAL VENTRAL HERNIA (SURGICAL REPAIR PROCEDURE)
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNKNOWN DOSE OR MEDICATION--RECORDS NOTE ONLY GENERAL ANESTHESIA WITH ENDOTRACHEAL TUBE
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	

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Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐ Respiratory (Inhalation) ☐ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ■ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 JAN 2021
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
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Name of Medication	ONDANSETRON
Prophylaxis	Yes ☐ No ■
Indication	INCARCERATED VENTRAL HERNIA
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 ☐

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	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)*	10 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	10 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ■
Indication	INCARCERATED VENTRAL HERNIA
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ■ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ■
Indication	INCARCERATED VENTRAL HERNIA
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)*	11 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 JAN 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 ■

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Name of Medication	MARCAINE WITH EPINEPHRINE (BUPIVACAINE 0.5% / EPINEPHRINE 1)
Prophylaxis	Yes ☐ No ■
Indication	INCARCERATED VENTRAL HERNIA
Dose per administration	20
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 ■

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	Transdermal ☐
	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
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Name of Medication	LOVENOX
Prophylaxis	Yes ■ No ☐
Indication	PREVENTION OF BLOOD CLOTS POST SURGICALLY
Dose per administration	40
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ■ Transdermal ☐

	Intraocular ☐
	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)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
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Name of Medication	NEURONTIN
Prophylaxis	Yes ☐ No ■
Indication	SENSORY NEUROPATHY
Dose per administration	800
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ■ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 JAN 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)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
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Name of Medication	DILAUDID
Prophylaxis	Yes ☐ No ■
Indication	INCARCERATED VENTRAL HERNIA
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)*	10 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	10 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Data signed: (b) (4) **09 Apr 2021 13:17:41**
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Name of Medication	DILAUDID
Prophylaxis	Yes ☐ No ■
Indication	INCARCERATED VENTRAL HERNIA
Dose per administration	0.25
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)*	12 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	DILAUDID
Prophylaxis	Yes ☐ No ■
Indication	INCARCERATED VENTRAL HERNIA
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	EVERY 3 HOURS AS NEEDED
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	13 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	NOVOLIN
Prophylaxis	Yes ☐
	No ■
Indication	TYPE 2 DIABETES MELLITUS
Dose per administration	0-12 SLIDING SCALE
Dose unit	mg ☐
	ug ☐
	mL ☐
	g ☐
	IU ■
	tablet ☐
	capsule ☐
	puff ☐
	Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐
	twice daily ☐
	three times daily ☐
	four times daily ☐
	every other day ☐
	every week ☐
	every month ☐
	as needed ■
	once ☐
	unknown ☐
	other ☐
If frequency is Other, specify	
Route of administration	Oral ☐
	Topical ☐
	Subcutaneous ■
	Transdermal ☐
	Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	13 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

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Name of Medication	LACTATED RINGERS
Prophylaxis	Yes ■ No ☐
Indication	PREVENTION OF DEHYDRATION, KEEP VEIN OPEN FOR IV MEDICATION ADMINISTRATION
Dose per administration	125
Dose unit	mg ☐ ug ☐ mL ■ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	PER HOUR
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)*	10 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	14 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
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Name of Medication	MELATONIN
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
Dose per administration	3
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	14 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	14 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 ■

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Data signed: (b) (4) **09 Apr 2021 13:17:41**
Generated On: 09 Jun 2021 15:40:20

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

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	ROXICODONE
Prophylaxis	Yes ☐ No ■
Indication	INCARCERATED VENTRAL HERNIA
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	EVERY 4 HOURS
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	PROTONIX
Prophylaxis	Yes ☐ No ■
Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	40
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	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)*	11 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 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 ■

Name of Medication	PROTONIX
Prophylaxis	Yes ☐ No ■
Indication	GASTRESOPHAGEAL REFLUX DISEASE
Dose per administration	40
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	13 JAN 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Data signed: (b) (4) **09 Apr 2021 13:17:41**
Generated On: 09 Jun 2021 15:40:20

Name of Medication	PHENOL 1.4% AEROSOL SPRAY (CHLORASEPTIC)
Prophylaxis	Yes ■ No ☐
Indication	IMPROVE NASOGASTRIC TUBE INSERTION PROCEDURE
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	SPRAY
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 ☐

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	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)*	10 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	10 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	PEPTO BISMOL CAPLETS (BRAND)
Prophylaxis	Yes ☐ No ■
Indication	DIARRHEA/VOMITING
Dose per administration	2
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)*	28 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	1 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 ☐

US3202036
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **09 Apr 2021 13:17:45**
Generated On: 09 Jun 2021 15:40:20

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

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US3202036
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) 09 Apr 2021 13:17:45
Generated On: 09 Jun 2021 15:40:20

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
10 JAN 2021	NASOGASTRIC TUBE PLACEMENT	Adverse Event	
12 JAN 2021	VENTRAL HERNIA REPAIR SURGERY	Adverse Event	

FDA-CBER-2022-1614-0428509

US3202036
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 15:40:20

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

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

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Data signed: (b) (4) **09 Apr 2021 13:17:45**
Generated On: 09 Jun 2021 15:40:20

SAEID	USA-US128-2021-MRNA-1273-P301000007
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form (1)
Data signed: (b) (4) 09 Apr 2021 13:17:45
Generated On: 09 Jun 2021 15:40:20

SAEID	USA-US128-2021-MRNA-1273-P301000007
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/JAN/2021 16:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-0428513

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form (2)
Data signed: (b) (4) 09 Apr 2021 13:17:45
Generated On: 09 Jun 2021 15:40:20

SAEID	USA-US128-2021-MRNA-1273-P301000007
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/JAN/2021 14:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-0428514

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form (3)
Data signed: (b) (4) 09 Apr 2021 13:17:45
Generated On: 09 Jun 2021 15:40:20

SAEID	USA-US128-2021-MRNA-1273-P301000007
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/JAN/2021 12:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form (4)
Data signed: (b) (4) 09 Apr 2021 13:17:45
Generated On: 09 Jun 2021 15:40:20

SAEID	USA-US128-2021-MRNA-1273-P301000007
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/JAN/2021 11:20
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

US3202036 (Prod: WR-ClinSearch, LLC)

FDA-CBER-2022-1614-0428517

US3202036
Form: Participant Creation
Generated On: 09 Jun 2021 15:40:20
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 21:31:18
User entered 'US3202036'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:09:32

FDA-CBER-2022-1614-0428518

US3202036
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:44:51

US3202036
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:09:33

FDA-CBER-2022-1614-0428520

US3202036
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:44:51

FDA-CBER-2022-1614-0428521

US3202036
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'SCRN'	System	06 Aug 2020 16:44:51

FDA-CBER-2022-1614-0428522

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:09:34

FDA-CBER-2022-1614-0428523

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '66'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

FDA-CBER-2022-1614-0428524

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User entered 'YEARS'	System	25 Aug 2020 17:17:19

FDA-CBER-2022-1614-0428525

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User entered '66'	System	06 Aug 2020 16:45:12

FDA-CBER-2022-1614-0428526

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Female (F)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Not Reported (NOT REPORTED)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

FDA-CBER-2022-1614-0428529

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

FDA-CBER-2022-1614-0428534

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

US3202036
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:20
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '1'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:17:19

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US3202036
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:20
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 16:30:19
User entered '6 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:45:12

US3202036
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:20
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User entered 'Aug 2020'	System	06 Aug 2020 16:45:12

US3202036
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:20
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User entered '2020'	System	06 Aug 2020 16:45:12

FDA-CBER-2022-1614-0428540

US3202036
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:20
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 16:30:19
User entered 'Amendment 1 (1)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:45:12

FDA-CBER-2022-1614-0428541

US3202036
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:20
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 16:30:19
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:45:12

US3202036
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:20
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 16:30:19
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:45:12

US3202036
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:20
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 16:30:19
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:45:12

US3202036
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:20
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 16:30:19
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:45:12

US3202036
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:20
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
DataPoint Verified.	(b) (4), (b) (6)	01 Sep 2020 16:30:19
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:09:33

FDA-CBER-2022-1614-0428546

US3202036
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:20
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User entered '1'	System	06 Aug 2020 16:45:19

US3202036
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 15:40:20
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:45:19

FDA-CBER-2022-1614-0428548

US3202036
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 15:40:20
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:45

FDA-CBER-2022-1614-0428549

US3202036
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
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)	29 Aug 2020 15:40:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:40:37
Data point term sent to Coder	System	29 Aug 2020 15:39:31
User entered 'Seasonal allergies'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:05

US3202036
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:40:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'UN UNK 2000' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 14:28:20
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:05

US3202036
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 14:28:20
User entered '1'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:05

US3202036
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:40:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:05

US3202036
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:40:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:05

US3202036
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:40:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:05

US3202036
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:40:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 2000'	System	16 Sep 2020 14:28:20
User entered empty.	System	29 Aug 2020 15:39:05

US3202036
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:40:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '2000'	System	16 Sep 2020 14:28:20
User entered empty.	System	29 Aug 2020 15:39:05

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US3202036
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:40:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:39:05

FDA-CBER-2022-1614-0428558

US3202036
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:40:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:39:05

FDA-CBER-2022-1614-0428559

US3202036
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:48:15
Query 'Per CDM: Response noted 'not ongoing per data entered so no ongoing meds' however, response to 'Condition ongoing at study entry is 'YES'? Please review and update accordingly. If Condition (Mild Asthma) is 'Ongoing' then please add a Con Med or provide an explanation for no medical treatment. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 09:58:21
User opened query 'Per CDM: Response noted 'not ongoing per data entered so no ongoing meds' however, response to 'Condition ongoing at study entry is 'YES'? Please review and update accordingly. If Condition (Mild Asthma) is 'Ongoing' then please add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:13:49
User closed query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:13:25
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:33:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:33:40
Data point term sent to Coder	System	16 Sep 2020 14:32:38
Coding entries removed.	Erica Osmundsen (b) (4)	16 Sep 2020 14:32:27
User entered 'MILD ASTHMA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 14:32:27

US3202036
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'not ongoing per data entered so no ongoing meds' (Site from DM).	Erica Osmundsen (b) (4)	16 Sep 2020 03:16:16
User opened query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:35:55
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:40:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:40:37
Data point term sent to Coder	System	29 Aug 2020 15:39:32
User entered 'Asthma'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:16

FDA-CBER-2022-1614-0428561

US3202036
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:40:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'UN UNK 1959' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 14:32:27
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:16

US3202036
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 14:32:27
User entered '1'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:16

US3202036
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:40:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 14:32:27
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:16

US3202036
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:40:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:16

US3202036
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:40:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 14:32:27
User entered '1'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:16

US3202036
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:40:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 1959'	System	16 Sep 2020 14:32:27
User entered empty.	System	29 Aug 2020 15:39:16

US3202036
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:40:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '1959'	System	16 Sep 2020 14:32:27
User entered empty.	System	29 Aug 2020 15:39:16

FDA-CBER-2022-1614-0428568

US3202036
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:40:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:39:16

FDA-CBER-2022-1614-0428569

US3202036
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:40:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:39:16

FDA-CBER-2022-1614-0428570

US3202036
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:41:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:41:38
Data point term sent to Coder	System	29 Aug 2020 15:40:33
User entered 'Hyperlipedema'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:40

FDA-CBER-2022-1614-0428571

US3202036
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'un Mar 2020'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:40

FDA-CBER-2022-1614-0428572

US3202036
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:40

FDA-CBER-2022-1614-0428573

US3202036
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:40

US3202036
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:40

US3202036
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:39:40

US3202036
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Mar 2020'	System	29 Aug 2020 15:39:40

FDA-CBER-2022-1614-0428577

US3202036
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '2020'	System	29 Aug 2020 15:39:40

FDA-CBER-2022-1614-0428578

US3202036
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:39:40

FDA-CBER-2022-1614-0428579

US3202036
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:39:40

FDA-CBER-2022-1614-0428580

US3202036
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:42:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:42:38
Data point term sent to Coder	System	29 Aug 2020 15:41:33
User entered 'Endometriosis'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:27

US3202036
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:40:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'un UNK 1982'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:27

FDA-CBER-2022-1614-0428582

US3202036
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:27

FDA-CBER-2022-1614-0428583

US3202036
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:40:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of #8 TOTAL HYSTERECTOMY was performed in UN UNK 1986 that may have resolved this condition. Please review and update if appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 21:50:49
Query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of #8 TOTAL HYSTERECTOMY was performed in UN UNK 1986 that may have resolved this condition. Please review and update if appropriate. Otherwise, clarify. ' answered with 'corrected' (Site from DM).	Erica Osmundsen (b) (4)	16 Sep 2020 03:18:43
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:18:29
User opened query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of #8 TOTAL HYSTERECTOMY was performed in UN UNK 1986 that may have resolved this condition. Please review and update if appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:37:08
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:27

US3202036
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:40:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'UN UNK 1986' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:19:05
User entered 'un UNK 1982' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:18:29
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:27

US3202036
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:40:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:27

US3202036
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:40:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 1982'	System	29 Aug 2020 15:41:27

US3202036
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:40:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '1982'	System	29 Aug 2020 15:41:27

FDA-CBER-2022-1614-0428588

US3202036
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:40:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 1986'	System	16 Sep 2020 03:19:05
User entered 'Jan 1982'	System	16 Sep 2020 03:18:29
User entered empty.	System	29 Aug 2020 15:41:27

US3202036
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:40:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '1986'	System	16 Sep 2020 03:19:05
User entered '1982'	System	16 Sep 2020 03:18:29
User entered empty.	System	29 Aug 2020 15:41:27

US3202036
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:30:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:30:42
Data point term sent to Coder	System	16 Sep 2020 14:29:36
Coding entries removed.	Erica Osmundsen (b) (4)	16 Sep 2020 14:29:01
User entered 'TOTAL HYSTERECTOMY' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 14:29:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 05:07:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 05:07:55
Data point term sent to Coder	System	29 Aug 2020 15:42:34
User entered 'Total Hysterectomy, indication unknown'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:54

US3202036
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'un UNK 1986'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:54

US3202036
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:54

US3202036
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:54

US3202036
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'un UNK 1986'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:54

US3202036
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:41:54

US3202036
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 1986'	System	29 Aug 2020 15:41:54

FDA-CBER-2022-1614-0428597

US3202036
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '1986'	System	29 Aug 2020 15:41:54

FDA-CBER-2022-1614-0428598

US3202036
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 1986'	System	29 Aug 2020 15:41:54

FDA-CBER-2022-1614-0428599

US3202036
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '1986'	System	29 Aug 2020 15:41:54

FDA-CBER-2022-1614-0428600

US3202036
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 21:51:50
Query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Fixed' (Site from DM).	zackery harmon (b) (4) (b) (4)	16 Sep 2020 15:28:33
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:34:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:34:45
Data point term sent to Coder	System	16 Sep 2020 14:33:43
Coding entries removed.	Erica Osmundsen (b) (4)	16 Sep 2020 14:33:34
User entered 'TYPE 2 DIABETES MELLITUS' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 14:33:34
User opened query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:38:37

US3202036
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 16:59:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 16:59:44
Data point term sent to Coder	System	29 Aug 2020 15:43:37
User entered 'DM T2'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:43:09

US3202036
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'un UNK 2015'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:43:09

FDA-CBER-2022-1614-0428603

US3202036
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:43:09

US3202036
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:43:09

US3202036
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:43:09

US3202036
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:43:09

US3202036
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 2015'	System	29 Aug 2020 15:43:09

FDA-CBER-2022-1614-0428608

US3202036
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '2015'	System	29 Aug 2020 15:43:09

FDA-CBER-2022-1614-0428609

US3202036
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:43:09

FDA-CBER-2022-1614-0428610

US3202036
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:43:09

FDA-CBER-2022-1614-0428611

US3202036
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:40:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:40:01
Data point term sent to Coder	System	29 Aug 2020 15:44:38
User entered 'Neuropathy caused by back surgery'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:19

FDA-CBER-2022-1614-0428612

US3202036
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:40:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'un UNK 2003'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:19

US3202036
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:19

US3202036
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:40:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:19

US3202036
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:40:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:19

US3202036
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:40:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:19

US3202036
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:40:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 2003'	System	29 Aug 2020 15:44:19

FDA-CBER-2022-1614-0428618

US3202036
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:40:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '2003'	System	29 Aug 2020 15:44:19

FDA-CBER-2022-1614-0428619

US3202036
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:40:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:44:19

FDA-CBER-2022-1614-0428620

US3202036
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:40:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:44:19

FDA-CBER-2022-1614-0428621

US3202036
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:46:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:46:40
Data point term sent to Coder	System	29 Aug 2020 15:45:40
User entered 'Back pain'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:51

US3202036
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:40:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'un UNK 2019'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:51

FDA-CBER-2022-1614-0428623

US3202036
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:51

US3202036
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:40:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:51

US3202036
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:40:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:51

US3202036
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:40:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:44:51

US3202036
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:40:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 2019'	System	29 Aug 2020 15:44:51

FDA-CBER-2022-1614-0428628

US3202036
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:40:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '2019'	System	29 Aug 2020 15:44:51

FDA-CBER-2022-1614-0428629

US3202036
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:40:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:44:51

FDA-CBER-2022-1614-0428630

US3202036
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:40:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	29 Aug 2020 15:44:51

FDA-CBER-2022-1614-0428631

US3202036
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:47:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 15:47:40
Data point term sent to Coder	System	29 Aug 2020 15:46:41
User entered 'Appendectomy'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:46:00

FDA-CBER-2022-1614-0428632

US3202036
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:40:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'un UNK 1961'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:46:00

US3202036
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:46:00

US3202036
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:40:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:46:00

US3202036
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:40:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'un UNK 1961'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:46:00

US3202036
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:40:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:46:00

US3202036
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:40:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 1961'	System	29 Aug 2020 15:46:00

FDA-CBER-2022-1614-0428638

US3202036
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:40:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '1961'	System	29 Aug 2020 15:46:00

FDA-CBER-2022-1614-0428639

US3202036
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:40:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 1961'	System	29 Aug 2020 15:46:00

FDA-CBER-2022-1614-0428640

US3202036
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:40:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '1961'	System	29 Aug 2020 15:46:00

FDA-CBER-2022-1614-0428641

US3202036
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:20:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:20:49
Data point term sent to Coder	System	17 Nov 2020 18:19:37
User entered 'GERD'	(b) (4), (b) (6)	17 Nov 2020 18:18:40

FDA-CBER-2022-1614-0428642

US3202036
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:40:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:48:15
User entered 'UN UNK 2018'	(b) (4), (b) (6) (b) (4)	17 Nov 2020 18:18:40

US3202036
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:48:15
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:18:40

FDA-CBER-2022-1614-0428644

US3202036
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:40:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 18:18:40

US3202036
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:40:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:48:15
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:18:40

US3202036
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:40:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:48:15
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:18:40

US3202036
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:40:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 2018'	System	17 Nov 2020 18:18:40

FDA-CBER-2022-1614-0428648

US3202036
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:40:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '2018'	System	17 Nov 2020 18:18:40

FDA-CBER-2022-1614-0428649

US3202036
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:40:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	17 Nov 2020 18:18:40

FDA-CBER-2022-1614-0428650

US3202036
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:40:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	17 Nov 2020 18:18:40

FDA-CBER-2022-1614-0428651

US3202036
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:40:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Incarcerated incisional hernia, LLT: Incarcerated incisional hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 01:14:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 01:14:08
Data point term sent to Coder	System	14 Jan 2021 22:33:36
User entered 'INCARCERATED RECURRENT INCISIONAL VENTRAL HERNIA'	Erica Osmundsen (b) (4)	14 Jan 2021 22:33:09

FDA-CBER-2022-1614-0428652

US3202036
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:40:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'UN UNK 2016'	Erica Osmundsen (b) (4)	14 Jan 2021 22:33:09

FDA-CBER-2022-1614-0428653

US3202036
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	Erica Osmundsen (b) (4)	14 Jan 2021 22:33:09

US3202036
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:40:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	14 Jan 2021 22:33:09

US3202036
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:40:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	Erica Osmundsen (b) (4)	14 Jan 2021 22:33:09

US3202036
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:40:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	Erica Osmundsen (b) (4)	14 Jan 2021 22:33:09

US3202036
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:40:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'Jan 2016'	System	14 Jan 2021 22:33:09

FDA-CBER-2022-1614-0428658

US3202036
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:40:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '2016'	System	14 Jan 2021 22:33:09

FDA-CBER-2022-1614-0428659

US3202036
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:40:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	14 Jan 2021 22:33:09

FDA-CBER-2022-1614-0428660

US3202036
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:40:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered empty.	System	14 Jan 2021 22:33:09

FDA-CBER-2022-1614-0428661

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '6 Aug 2020'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '12:30'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23

FDA-CBER-2022-1614-0428664

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered '6 Aug 2020 12:30'	System	25 Aug 2020 17:18:23

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '160.7' cm	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23
DataPoint set to visible.	System	06 Aug 2020 16:45:19

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '83.0' kg	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23
DataPoint set to visible.	System	06 Aug 2020 16:45:19

FDA-CBER-2022-1614-0428667

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
Amendment Manager: User entered '32.14003'	System	16 Sep 2020 23:45:38
User entered '32.1'	System	25 Aug 2020 17:18:23
DataPoint set to visible.	System	06 Aug 2020 16:45:19

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'kg/m2'	System	25 Aug 2020 17:18:23
DataPoint set to visible.	System	06 Aug 2020 16:45:19

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'bpm'	System	25 Aug 2020 17:18:23

FDA-CBER-2022-1614-0428674

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23

FDA-CBER-2022-1614-0428675

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'breaths/min'	System	25 Aug 2020 17:18:23

FDA-CBER-2022-1614-0428676

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23

FDA-CBER-2022-1614-0428677

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'mmHg'	System	25 Aug 2020 17:18:23

FDA-CBER-2022-1614-0428678

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:23

FDA-CBER-2022-1614-0428679

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User entered 'mmHg'	System	25 Aug 2020 17:18:23

FDA-CBER-2022-1614-0428680

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54

FDA-CBER-2022-1614-0428681

US3202036
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54

FDA-CBER-2022-1614-0428682

US3202036
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:20
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:38:03
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:28

US3202036
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:20
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
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 10:12:31
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 18:16:47
User entered '06 Aug 2020' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:38:03
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:18:28

US3202036
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:40:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '6 Aug 2020'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:03

US3202036
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:40:20
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:03

US3202036
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:40:20
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Surgically sterile (SURGICALLY STERILE)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:03

US3202036
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:40:20
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:03

US3202036
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:40:20
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'UN UNK 1986' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Oct 2020 14:40:02
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:03

US3202036
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:40:20
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per DM CLR: Date of surgery unknown = Yes, however, the corresponding recorded procedure in the Med History eCRF has a date of 1986. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:53:33
Query 'Per DM CLR: Date of surgery unknown = Yes, however, the corresponding recorded procedure in the Med History eCRF has a date of 1986. Please reconcile and update as appropriate, otherwise provide clarification.' answered with 'UPDATED' (Site from DM).	Erica Osmundsen (b) (4)	09 Oct 2020 14:40:06
User entered '0' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Oct 2020 14:40:02
User opened query 'Per DM CLR: Date of surgery unknown = Yes, however, the corresponding recorded procedure in the Med History eCRF has a date of 1986. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:38:42
User entered '1'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:03

US3202036
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:40:20

If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:03

US3202036
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:40:20
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:36:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:03

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20

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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

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US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

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US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

FDA-CBER-2022-1614-0428706

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
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 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '1'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

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US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '0'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:20
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:37:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:19:40

US3202036
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:45:35

FDA-CBER-2022-1614-0428714

US3202036
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '6 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:45:35

FDA-CBER-2022-1614-0428715

US3202036
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 16:45:35

US3202036
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'VISIT1'	System	06 Aug 2020 16:45:35

FDA-CBER-2022-1614-0428717

US3202036
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:40:20
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:29:15

FDA-CBER-2022-1614-0428718

US3202036
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:40:20
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:33:04
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:33:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 16:29:15
User entered '184969' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:29:15

US3202036
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:40:20
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:29:15

FDA-CBER-2022-1614-0428720

US3202036
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:40:20
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)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:20:09

FDA-CBER-2022-1614-0428721

US3202036
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:40:20
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)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:20:09

US3202036
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:40:20
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:20:09

FDA-CBER-2022-1614-0428723

US3202036
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:40:20
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:20:09

FDA-CBER-2022-1614-0428724

US3202036
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:40:20
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:20:09

FDA-CBER-2022-1614-0428725

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:20
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:55:18
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:17
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:51:07
User entered '160.7' cm	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428726

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:20
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:55:19
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:29
User entered missing code ND - Not Done; reason for change Data Entry Error	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:17
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:51:11
User entered '83.0' kg	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428727

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:20
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:55:18
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:17
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:51:07
User entered '160.7' cm	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428728

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:20
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:55:19
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:29
User entered missing code ND - Not Done; reason for change Data Entry Error	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:17
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:51:11
User entered '83.0' kg	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428730

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428731

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '6 Aug 2020'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428732

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '12:30'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '6 Aug 2020 12:30'	System	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428734

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '36.7' C	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428737

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '73'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428738

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'bpm'	System	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428739

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '18'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428740

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'breaths/min'	System	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428741

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '124'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428742

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'mmHg'	System	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428743

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '76'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428744

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'mmHg'	System	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428745

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:20
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:55:18
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:17
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:51:07
User entered '160.7' cm	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:20
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:55:19
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:29
User entered missing code ND - Not Done; reason for change Data Entry Error	zackery harmon (b) (4) (b) (4)	24 Sep 2020 11:28:17
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:51:11
User entered '83.0' kg	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428748

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428749

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '6 Aug 2020'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '13:53'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428751

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '6 Aug 2020 13:53'	System	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428752

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '36.5' C	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428753

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428754

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428755

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '73'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428756

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'bpm'	System	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428757

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '18'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428758

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'breaths/min'	System	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428759

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '122'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428760

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'mmHg'	System	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428761

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '80'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428762

US3202036
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'mmHg'	System	25 Aug 2020 17:24:50

FDA-CBER-2022-1614-0428763

US3202036
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:20
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:38:19
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:59

FDA-CBER-2022-1614-0428764

US3202036
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:20
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:38:19
User entered '6 Aug 2020'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:24:59

US3202036
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	06 Aug 2020 17:24:06

US3202036
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	Erica Osmundsen (b) (4)	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428767

US3202036
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
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)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	Erica Osmundsen (b) (4)	06 Aug 2020 17:24:06

US3202036
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 17:24:06

US3202036
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '6 Aug 2020'	Erica Osmundsen (b) (4)	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428770

US3202036
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '13:03'	Erica Osmundsen (b) (4)	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428771

US3202036
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '6 Aug 2020 13:03'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428772

US3202036
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Left Arm (LEFT ARM)'	Erica Osmundsen (b) (4)	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428773

US3202036
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'ONCE'	System	06 Aug 2020 17:24:06

US3202036
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 17:24:06

US3202036
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:25:30

US3202036
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 06-AUG-2020. However, test result date is missing in GCL. Please confirm if 06-AUG-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:37:37
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 06-AUG-2020. However, test result date is missing in GCL. Please confirm if 06-AUG-2020 is correct date to update in GCL records.' answered with 'Yes, this is the correct date.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:29:30
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 06-AUG-2020. However, test result date is missing in GCL. Please confirm if 06-AUG-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:46:19
User entered '6 Aug 2020'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:25:30

FDA-CBER-2022-1614-0428777

US3202036
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '12:38'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:25:30

US3202036
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '6 Aug 2020 12:38'	System	25 Aug 2020 17:25:30

FDA-CBER-2022-1614-0428779

US3202036
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 15:40:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '6 Aug 2020'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:25:49

US3202036
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:40:20
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:25:49

US3202036
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:40:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:25:49

FDA-CBER-2022-1614-0428782

US3202036
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:40:20
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '12:36'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:25:49

US3202036
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:40:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '6 Aug 2020 12:36'	System	25 Aug 2020 17:25:49

FDA-CBER-2022-1614-0428784

US3202036
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:40:20
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:25:49

US3202036
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:40:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:25:49

US3202036
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:40:20
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:25:49

FDA-CBER-2022-1614-0428787

US3202036
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:40:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered empty.	System	25 Aug 2020 17:25:49

FDA-CBER-2022-1614-0428788

US3202036
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	25 Aug 2020 17:25:55

FDA-CBER-2022-1614-0428789

US3202036
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '1'	System	25 Aug 2020 17:25:55

FDA-CBER-2022-1614-0428790

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:24:06

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:51:05', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6a90f38-c9ac-4077-ba96-f70dbb9fc817'	System	06 Aug 2020 17:52:14
User entered 'Yes (Y)'	System	06 Aug 2020 17:52:14

FDA-CBER-2022-1614-0428792

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:51:27', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6a90f38-c9ac-4077-ba96-f70dbb9fc817'	System	06 Aug 2020 17:52:14
User entered '97.7'	System	06 Aug 2020 17:52:14

FDA-CBER-2022-1614-0428793

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:51:38', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6a90f38-c9ac-4077-ba96-f70dbb9fc817'	System	06 Aug 2020 17:52:14
User entered 'No (N)'	System	06 Aug 2020 17:52:14

FDA-CBER-2022-1614-0428794

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:52:09', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6a90f38-c9ac-4077-ba96-f70dbb9fc817'	System	06 Aug 2020 17:52:14
User entered '06 Aug 2020 13:52'	System	06 Aug 2020 17:52:14

FDA-CBER-2022-1614-0428795

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Aug 2020 13:23'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428796

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Aug 2020 15:53'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428797

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428798

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:41:41', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '69368ad9-c3e5-4bc4-92c6-13745f87ce55'	System	06 Aug 2020 21:42:22
User entered 'Yes (Y)'	System	06 Aug 2020 21:42:22

FDA-CBER-2022-1614-0428799

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:41:50', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '69368ad9-c3e5-4bc4-92c6-13745f87ce55'	System	06 Aug 2020 21:42:22
User entered '97.7'	System	06 Aug 2020 21:42:22

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:41:57', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '69368ad9-c3e5-4bc4-92c6-13745f87ce55'	System	06 Aug 2020 21:42:22
User entered 'No (N)'	System	06 Aug 2020 21:42:22

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:42:20', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '69368ad9-c3e5-4bc4-92c6-13745f87ce55'	System	06 Aug 2020 21:42:22
User entered '06 Aug 2020 17:42'	System	06 Aug 2020 21:42:22

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Aug 2020 16:48'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428803

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428804

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 2'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428805

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:52:05', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3b7d47f2-c198-4202-83fb-93ad280523a1'	System	07 Aug 2020 21:52:27
User entered 'Yes (Y)'	System	07 Aug 2020 21:52:27

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:52:12', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3b7d47f2-c198-4202-83fb-93ad280523a1'	System	07 Aug 2020 21:52:27
User entered '96.3'	System	07 Aug 2020 21:52:27

FDA-CBER-2022-1614-0428807

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:52:18', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3b7d47f2-c198-4202-83fb-93ad280523a1'	System	07 Aug 2020 21:52:27
User entered 'No (N)'	System	07 Aug 2020 21:52:27

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:52:26', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3b7d47f2-c198-4202-83fb-93ad280523a1'	System	07 Aug 2020 21:52:27
User entered '07 Aug 2020 17:52'	System	07 Aug 2020 21:52:27

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428810

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428811

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 3'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428812

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:19:42', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f81139c3-7b62-4216-994a-866316563c12'	System	08 Aug 2020 21:20:07
User entered 'Yes (Y)'	System	08 Aug 2020 21:20:07

FDA-CBER-2022-1614-0428813

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:19:49', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f81139c3-7b62-4216-994a-866316563c12'	System	08 Aug 2020 21:20:07
User entered '98.1'	System	08 Aug 2020 21:20:07

FDA-CBER-2022-1614-0428814

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:19:54', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f81139c3-7b62-4216-994a-866316563c12'	System	08 Aug 2020 21:20:07
User entered 'No (N)'	System	08 Aug 2020 21:20:07

FDA-CBER-2022-1614-0428815

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:20:03', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f81139c3-7b62-4216-994a-866316563c12'	System	08 Aug 2020 21:20:07
User entered '08 Aug 2020 17:20'	System	08 Aug 2020 21:20:07

FDA-CBER-2022-1614-0428816

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428817

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428818

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 4'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428819

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:42:24', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6807466f-3b3a-41da-ac30-bce55b07040c'	System	09 Aug 2020 22:42:41
User entered 'Yes (Y)'	System	09 Aug 2020 22:42:41

FDA-CBER-2022-1614-0428820

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:42:32', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6807466f-3b3a-41da-ac30-bce55b07040c'	System	09 Aug 2020 22:42:41
User entered '98.3'	System	09 Aug 2020 22:42:41

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:42:36', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6807466f-3b3a-41da-ac30-bce55b07040c'	System	09 Aug 2020 22:42:41
User entered 'No (N)'	System	09 Aug 2020 22:42:41

FDA-CBER-2022-1614-0428822

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:42:40', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6807466f-3b3a-41da-ac30-bce55b07040c'	System	09 Aug 2020 22:42:41
User entered '09 Aug 2020 18:42'	System	09 Aug 2020 22:42:41

FDA-CBER-2022-1614-0428823

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428824

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428825

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 5'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428826

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:27:46', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'c0a0bff6-47de-4af3-8b65-e098ad95b58c'	System	10 Aug 2020 21:28:20
User entered 'Yes (Y)'	System	10 Aug 2020 21:28:20

FDA-CBER-2022-1614-0428827

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:08', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'c0a0bff6-47de-4af3-8b65-e098ad95b58c'	System	10 Aug 2020 21:28:20
User entered '98.3'	System	10 Aug 2020 21:28:20

FDA-CBER-2022-1614-0428828

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:12', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'c0a0bff6-47de-4af3-8b65-e098ad95b58c'	System	10 Aug 2020 21:28:20
User entered 'No (N)'	System	10 Aug 2020 21:28:20

FDA-CBER-2022-1614-0428829

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:16', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'c0a0bff6-47de-4af3-8b65-e098ad95b58c'	System	10 Aug 2020 21:28:20
User entered '10 Aug 2020 17:28'	System	10 Aug 2020 21:28:20

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428831

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428832

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 6'	System	06 Aug 2020 17:24:06

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:01:15', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f82aee47-9015-4a64-9d59-e2e203a3d116'	System	11 Aug 2020 23:02:28
User entered 'Yes (Y)'	System	11 Aug 2020 23:02:28

FDA-CBER-2022-1614-0428834

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:02:18', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f82aee47-9015-4a64-9d59-e2e203a3d116'	System	11 Aug 2020 23:02:28
User entered '97.5'	System	11 Aug 2020 23:02:28

FDA-CBER-2022-1614-0428835

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:02:21', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f82aee47-9015-4a64-9d59-e2e203a3d116'	System	11 Aug 2020 23:02:28
User entered 'No (N)'	System	11 Aug 2020 23:02:28

FDA-CBER-2022-1614-0428836

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:02:26', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f82aee47-9015-4a64-9d59-e2e203a3d116'	System	11 Aug 2020 23:02:28
User entered '11 Aug 2020 19:02'	System	11 Aug 2020 23:02:28

FDA-CBER-2022-1614-0428837

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428838

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428839

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 7'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428840

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:18:54', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'fd02b80d-0ab0-4591-841d-c5d8de7d2b8c'	System	12 Aug 2020 22:19:33
User entered 'Yes (Y)'	System	12 Aug 2020 22:19:33

FDA-CBER-2022-1614-0428841

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:19:13', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'fd02b80d-0ab0-4591-841d-c5d8de7d2b8c'	System	12 Aug 2020 22:19:33
User entered '98.1'	System	12 Aug 2020 22:19:33

FDA-CBER-2022-1614-0428842

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:19:27', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'fd02b80d-0ab0-4591-841d-c5d8de7d2b8c'	System	12 Aug 2020 22:19:33
User entered 'No (N)'	System	12 Aug 2020 22:19:33

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:19:31', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'fd02b80d-0ab0-4591-841d-c5d8de7d2b8c'	System	12 Aug 2020 22:19:33
User entered '12 Aug 2020 18:19'	System	12 Aug 2020 22:19:33

FDA-CBER-2022-1614-0428844

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428845

US3202036
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428846

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428847

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:52:24', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f411fc93-94b8-4a46-8b36-5a60a8f1897f'	System	06 Aug 2020 17:53:36
User entered 'None (1)'	System	06 Aug 2020 17:53:36

FDA-CBER-2022-1614-0428848

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:52:35', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f411fc93-94b8-4a46-8b36-5a60a8f1897f'	System	06 Aug 2020 17:53:36
User entered 'No (N)'	System	06 Aug 2020 17:53:36

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:52:39', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f411fc93-94b8-4a46-8b36-5a60a8f1897f'	System	06 Aug 2020 17:53:36
User entered 'No (N)'	System	06 Aug 2020 17:53:36

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:53:22', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f411fc93-94b8-4a46-8b36-5a60a8f1897f'	System	06 Aug 2020 17:53:36
User entered 'None (1)'	System	06 Aug 2020 17:53:36

FDA-CBER-2022-1614-0428851

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:53:33', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f411fc93-94b8-4a46-8b36-5a60a8f1897f'	System	06 Aug 2020 17:53:36
User entered '06 Aug 2020 13:53'	System	06 Aug 2020 17:53:36

FDA-CBER-2022-1614-0428852

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Aug 2020 13:23'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428853

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Aug 2020 15:53'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428854

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:24:06

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:42:45', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '1736f6d8-cf2b-406d-811f-9a289002861b'	System	06 Aug 2020 21:43:59
User entered 'None (1)'	System	06 Aug 2020 21:43:59

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:42:56', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '1736f6d8-cf2b-406d-811f-9a289002861b'	System	06 Aug 2020 21:43:59
User entered 'No (N)'	System	06 Aug 2020 21:43:59

FDA-CBER-2022-1614-0428857

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:43:02', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '1736f6d8-cf2b-406d-811f-9a289002861b'	System	06 Aug 2020 21:43:59
User entered 'No (N)'	System	06 Aug 2020 21:43:59

FDA-CBER-2022-1614-0428858

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:43:13', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '1736f6d8-cf2b-406d-811f-9a289002861b'	System	06 Aug 2020 21:43:59
User entered 'None (1)'	System	06 Aug 2020 21:43:59

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:43:55', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '1736f6d8-cf2b-406d-811f-9a289002861b'	System	06 Aug 2020 21:43:59
User entered '06 Aug 2020 17:43'	System	06 Aug 2020 21:43:59

FDA-CBER-2022-1614-0428860

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Aug 2020 16:48'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428861

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428862

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 2'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428863

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:52:40', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '41b528e7-b209-4ecf-87a8-c4f5005a0b5f'	System	07 Aug 2020 21:53:16
User entered 'None (1)'	System	07 Aug 2020 21:53:16

FDA-CBER-2022-1614-0428864

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:52:50', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '41b528e7-b209-4ecf-87a8-c4f5005a0b5f'	System	07 Aug 2020 21:53:16
User entered 'No (N)'	System	07 Aug 2020 21:53:16

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:52:55', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '41b528e7-b209-4ecf-87a8-c4f5005a0b5f'	System	07 Aug 2020 21:53:16
User entered 'No (N)'	System	07 Aug 2020 21:53:16

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:53:05', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '41b528e7-b209-4ecf-87a8-c4f5005a0b5f'	System	07 Aug 2020 21:53:16
User entered 'None (1)'	System	07 Aug 2020 21:53:16

FDA-CBER-2022-1614-0428867

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:53:12', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '41b528e7-b209-4ecf-87a8-c4f5005a0b5f'	System	07 Aug 2020 21:53:16
User entered '07 Aug 2020 17:53'	System	07 Aug 2020 21:53:16

FDA-CBER-2022-1614-0428868

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428869

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428870

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 3'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428871

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:20:08', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'df0bad99-e54d-42dc-89f7-1635ee02e611'	System	08 Aug 2020 21:20:38
User entered 'None (1)'	System	08 Aug 2020 21:20:38

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:20:14', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'df0bad99-e54d-42dc-89f7-1635ee02e611'	System	08 Aug 2020 21:20:38
User entered 'No (N)'	System	08 Aug 2020 21:20:38

FDA-CBER-2022-1614-0428873

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:20:20', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'df0bad99-e54d-42dc-89f7-1635ee02e611'	System	08 Aug 2020 21:20:38
User entered 'No (N)'	System	08 Aug 2020 21:20:38

FDA-CBER-2022-1614-0428874

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:20:25', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'df0bad99-e54d-42dc-89f7-1635ee02e611'	System	08 Aug 2020 21:20:38
User entered 'None (1)'	System	08 Aug 2020 21:20:38

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:20:34', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'df0bad99-e54d-42dc-89f7-1635ee02e611'	System	08 Aug 2020 21:20:38
User entered '08 Aug 2020 17:20'	System	08 Aug 2020 21:20:38

FDA-CBER-2022-1614-0428876

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428877

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428878

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 4'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428879

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:42:45', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '4521c6ad-a705-4215-9227-68e367c63072'	System	09 Aug 2020 22:43:07
User entered 'None (1)'	System	09 Aug 2020 22:43:07

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:42:49', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '4521c6ad-a705-4215-9227-68e367c63072'	System	09 Aug 2020 22:43:07
User entered 'No (N)'	System	09 Aug 2020 22:43:07

FDA-CBER-2022-1614-0428881

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:42:52', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '4521c6ad-a705-4215-9227-68e367c63072'	System	09 Aug 2020 22:43:07
User entered 'No (N)'	System	09 Aug 2020 22:43:07

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:42:59', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '4521c6ad-a705-4215-9227-68e367c63072'	System	09 Aug 2020 22:43:07
User entered 'None (1)'	System	09 Aug 2020 22:43:07

FDA-CBER-2022-1614-0428883

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:43:06', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '4521c6ad-a705-4215-9227-68e367c63072'	System	09 Aug 2020 22:43:07
User entered '09 Aug 2020 18:43'	System	09 Aug 2020 22:43:07

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428885

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428886

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 5'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428887

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:20', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'dee43d29-49c1-41ba-9c99-dc908bff4aec'	System	10 Aug 2020 21:28:41
User entered 'None (1)'	System	10 Aug 2020 21:28:41

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:25', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'dee43d29-49c1-41ba-9c99-dc908bff4aec'	System	10 Aug 2020 21:28:41
User entered 'No (N)'	System	10 Aug 2020 21:28:41

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:29', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'dee43d29-49c1-41ba-9c99-dc908bff4aec'	System	10 Aug 2020 21:28:41
User entered 'No (N)'	System	10 Aug 2020 21:28:41

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:34', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'dee43d29-49c1-41ba-9c99-dc908bff4aec'	System	10 Aug 2020 21:28:41
User entered 'None (1)'	System	10 Aug 2020 21:28:41

FDA-CBER-2022-1614-0428891

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:38', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'dee43d29-49c1-41ba-9c99-dc908bff4aec'	System	10 Aug 2020 21:28:41
User entered '10 Aug 2020 17:28'	System	10 Aug 2020 21:28:41

FDA-CBER-2022-1614-0428892

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428893

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428894

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 6'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428895

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:02:30', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd809f8e5-8402-4b25-9d42-0875487374ed'	System	11 Aug 2020 23:02:48
User entered 'None (1)'	System	11 Aug 2020 23:02:48

FDA-CBER-2022-1614-0428896

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:02:34', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd809f8e5-8402-4b25-9d42-0875487374ed'	System	11 Aug 2020 23:02:48
User entered 'No (N)'	System	11 Aug 2020 23:02:48

FDA-CBER-2022-1614-0428897

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:02:38', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd809f8e5-8402-4b25-9d42-0875487374ed'	System	11 Aug 2020 23:02:48
User entered 'No (N)'	System	11 Aug 2020 23:02:48

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:02:41', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd809f8e5-8402-4b25-9d42-0875487374ed'	System	11 Aug 2020 23:02:48
User entered 'None (1)'	System	11 Aug 2020 23:02:48

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:02:45', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd809f8e5-8402-4b25-9d42-0875487374ed'	System	11 Aug 2020 23:02:48
User entered '11 Aug 2020 19:02'	System	11 Aug 2020 23:02:48

FDA-CBER-2022-1614-0428900

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428901

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428902

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 7'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428903

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:19:37', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7ff27e8e-6d68-4c06-9275-387d03ebca4d'	System	12 Aug 2020 22:20:10
User entered 'None (1)'	System	12 Aug 2020 22:20:10

FDA-CBER-2022-1614-0428904

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:19:41', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7ff27e8e-6d68-4c06-9275-387d03ebca4d'	System	12 Aug 2020 22:20:10
User entered 'No (N)'	System	12 Aug 2020 22:20:10

FDA-CBER-2022-1614-0428905

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:19:47', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7ff27e8e-6d68-4c06-9275-387d03ebca4d'	System	12 Aug 2020 22:20:10
User entered 'No (N)'	System	12 Aug 2020 22:20:10

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:20:03', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7ff27e8e-6d68-4c06-9275-387d03ebca4d'	System	12 Aug 2020 22:20:10
User entered 'None (1)'	System	12 Aug 2020 22:20:10

FDA-CBER-2022-1614-0428907

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:20:06', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7ff27e8e-6d68-4c06-9275-387d03ebca4d'	System	12 Aug 2020 22:20:10
User entered '12 Aug 2020 18:20'	System	12 Aug 2020 22:20:10

FDA-CBER-2022-1614-0428908

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428909

US3202036
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428910

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:24:06

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:53:43', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2de0695e-865f-47b3-b45e-95df09ea2d03'	System	06 Aug 2020 17:54:29
User entered 'None (0)'	System	06 Aug 2020 17:54:29

FDA-CBER-2022-1614-0428912

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:53:52', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2de0695e-865f-47b3-b45e-95df09ea2d03'	System	06 Aug 2020 17:54:29
User entered 'None (0)'	System	06 Aug 2020 17:54:29

FDA-CBER-2022-1614-0428913

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:53:56', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2de0695e-865f-47b3-b45e-95df09ea2d03'	System	06 Aug 2020 17:54:29
User entered 'None (0)'	System	06 Aug 2020 17:54:29

FDA-CBER-2022-1614-0428914

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:54:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2de0695e-865f-47b3-b45e-95df09ea2d03'	System	06 Aug 2020 17:54:29
User entered 'None (0)'	System	06 Aug 2020 17:54:29

FDA-CBER-2022-1614-0428915

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:54:06', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2de0695e-865f-47b3-b45e-95df09ea2d03'	System	06 Aug 2020 17:54:29
User entered 'None (0)'	System	06 Aug 2020 17:54:29

FDA-CBER-2022-1614-0428916

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:54:11', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2de0695e-865f-47b3-b45e-95df09ea2d03'	System	06 Aug 2020 17:54:29
User entered 'None (0)'	System	06 Aug 2020 17:54:29

FDA-CBER-2022-1614-0428917

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:54:21', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2de0695e-865f-47b3-b45e-95df09ea2d03'	System	06 Aug 2020 17:54:29
User entered 'No (N)'	System	06 Aug 2020 17:54:29

FDA-CBER-2022-1614-0428918

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T13:54:27', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2de0695e-865f-47b3-b45e-95df09ea2d03'	System	06 Aug 2020 17:54:29
User entered '06 Aug 2020 13:54'	System	06 Aug 2020 17:54:29

FDA-CBER-2022-1614-0428919

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Aug 2020 13:23'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428920

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Aug 2020 15:53'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428921

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:24:06

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:44:14', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'be1417e3-2d4b-40fe-86bd-ae65786c8ddb'	System	06 Aug 2020 21:45:14
User entered 'None (0)'	System	06 Aug 2020 21:45:14

FDA-CBER-2022-1614-0428923

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:44:18', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'be1417e3-2d4b-40fe-86bd-ae65786c8ddb'	System	06 Aug 2020 21:45:14
User entered 'None (0)'	System	06 Aug 2020 21:45:14

FDA-CBER-2022-1614-0428924

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:44:22', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'be1417e3-2d4b-40fe-86bd-ae65786c8ddb'	System	06 Aug 2020 21:45:14
User entered 'None (0)'	System	06 Aug 2020 21:45:14

FDA-CBER-2022-1614-0428925

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:44:26', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'be1417e3-2d4b-40fe-86bd-ae65786c8ddb'	System	06 Aug 2020 21:45:14
User entered 'None (0)'	System	06 Aug 2020 21:45:14

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:44:30', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'be1417e3-2d4b-40fe-86bd-ae65786c8ddb'	System	06 Aug 2020 21:45:14
User entered 'None (0)'	System	06 Aug 2020 21:45:14

FDA-CBER-2022-1614-0428927

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:44:46', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'be1417e3-2d4b-40fe-86bd-ae65786c8ddb'	System	06 Aug 2020 21:45:14
User entered 'None (0)'	System	06 Aug 2020 21:45:14

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:44:58', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'be1417e3-2d4b-40fe-86bd-ae65786c8ddb'	System	06 Aug 2020 21:45:14
User entered 'No (N)'	System	06 Aug 2020 21:45:14

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-06T17:45:13', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'be1417e3-2d4b-40fe-86bd-ae65786c8ddb'	System	06 Aug 2020 21:45:14
User entered '06 Aug 2020 17:45'	System	06 Aug 2020 21:45:14

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Aug 2020 16:48'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428931

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428932

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 2'	System	06 Aug 2020 17:24:06

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:53:34', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'bfdcfd4a-2df8-4968-a184-80887625c9ef'	System	07 Aug 2020 21:54:18
User entered 'None (0)'	System	07 Aug 2020 21:54:18

FDA-CBER-2022-1614-0428934

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:53:42', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'bfdcfd4a-2df8-4968-a184-80887625c9ef'	System	07 Aug 2020 21:54:18
User entered 'None (0)'	System	07 Aug 2020 21:54:18

FDA-CBER-2022-1614-0428935

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:53:51', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'bfdcfd4a-2df8-4968-a184-80887625c9ef'	System	07 Aug 2020 21:54:18
User entered 'None (0)'	System	07 Aug 2020 21:54:18

FDA-CBER-2022-1614-0428936

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:53:56', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'bfdcfd4a-2df8-4968-a184-80887625c9ef'	System	07 Aug 2020 21:54:18
User entered 'None (0)'	System	07 Aug 2020 21:54:18

FDA-CBER-2022-1614-0428937

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:53:59', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'bfdcfd4a-2df8-4968-a184-80887625c9ef'	System	07 Aug 2020 21:54:18
User entered 'None (0)'	System	07 Aug 2020 21:54:18

FDA-CBER-2022-1614-0428938

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:54:02', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'bfdcfd4a-2df8-4968-a184-80887625c9ef'	System	07 Aug 2020 21:54:18
User entered 'None (0)'	System	07 Aug 2020 21:54:18

FDA-CBER-2022-1614-0428939

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:54:09', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'bfdcfd4a-2df8-4968-a184-80887625c9ef'	System	07 Aug 2020 21:54:18
User entered 'No (N)'	System	07 Aug 2020 21:54:18

FDA-CBER-2022-1614-0428940

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-07T17:54:15', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'bfdcfd4a-2df8-4968-a184-80887625c9ef'	System	07 Aug 2020 21:54:18
User entered '07 Aug 2020 17:54'	System	07 Aug 2020 21:54:18

FDA-CBER-2022-1614-0428941

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428942

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428943

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 3'	System	06 Aug 2020 17:24:06

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:20:42', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '48042860-0ae9-40a9-b0ae-872496d41ded'	System	08 Aug 2020 21:21:31
User entered 'None (0)'	System	08 Aug 2020 21:21:31

FDA-CBER-2022-1614-0428945

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:20:50', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '48042860-0ae9-40a9-b0ae-872496d41ded'	System	08 Aug 2020 21:21:31
User entered 'None (0)'	System	08 Aug 2020 21:21:31

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:20:55', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '48042860-0ae9-40a9-b0ae-872496d41ded'	System	08 Aug 2020 21:21:31
User entered 'None (0)'	System	08 Aug 2020 21:21:31

FDA-CBER-2022-1614-0428947

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:21:03', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '48042860-0ae9-40a9-b0ae-872496d41ded'	System	08 Aug 2020 21:21:31
User entered 'None (0)'	System	08 Aug 2020 21:21:31

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:21:12', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '48042860-0ae9-40a9-b0ae-872496d41ded'	System	08 Aug 2020 21:21:31
User entered 'None (0)'	System	08 Aug 2020 21:21:31

FDA-CBER-2022-1614-0428949

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:21:16', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '48042860-0ae9-40a9-b0ae-872496d41ded'	System	08 Aug 2020 21:21:31
User entered 'None (0)'	System	08 Aug 2020 21:21:31

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:21:20', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '48042860-0ae9-40a9-b0ae-872496d41ded'	System	08 Aug 2020 21:21:31
User entered 'No (N)'	System	08 Aug 2020 21:21:31

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-08T17:21:29', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '48042860-0ae9-40a9-b0ae-872496d41ded'	System	08 Aug 2020 21:21:31
User entered '08 Aug 2020 17:21'	System	08 Aug 2020 21:21:31

FDA-CBER-2022-1614-0428952

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428953

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428954

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 4'	System	06 Aug 2020 17:24:06

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:43:12', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd175c6d3-7851-41e7-a284-9ca8c64960b8'	System	09 Aug 2020 22:43:38
User entered 'None (0)'	System	09 Aug 2020 22:43:38

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:43:15', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd175c6d3-7851-41e7-a284-9ca8c64960b8'	System	09 Aug 2020 22:43:38
User entered 'None (0)'	System	09 Aug 2020 22:43:38

FDA-CBER-2022-1614-0428957

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:43:19', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd175c6d3-7851-41e7-a284-9ca8c64960b8'	System	09 Aug 2020 22:43:38
User entered 'None (0)'	System	09 Aug 2020 22:43:38

FDA-CBER-2022-1614-0428958

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:43:22', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd175c6d3-7851-41e7-a284-9ca8c64960b8'	System	09 Aug 2020 22:43:38
User entered 'None (0)'	System	09 Aug 2020 22:43:38

FDA-CBER-2022-1614-0428959

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:43:25', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd175c6d3-7851-41e7-a284-9ca8c64960b8'	System	09 Aug 2020 22:43:38
User entered 'None (0)'	System	09 Aug 2020 22:43:38

FDA-CBER-2022-1614-0428960

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:43:28', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd175c6d3-7851-41e7-a284-9ca8c64960b8'	System	09 Aug 2020 22:43:38
User entered 'None (0)'	System	09 Aug 2020 22:43:38

FDA-CBER-2022-1614-0428961

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:43:33', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd175c6d3-7851-41e7-a284-9ca8c64960b8'	System	09 Aug 2020 22:43:38
User entered 'No (N)'	System	09 Aug 2020 22:43:38

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-09T18:43:37', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd175c6d3-7851-41e7-a284-9ca8c64960b8'	System	09 Aug 2020 22:43:38
User entered '09 Aug 2020 18:43'	System	09 Aug 2020 22:43:38

FDA-CBER-2022-1614-0428963

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428964

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428965

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 5'	System	06 Aug 2020 17:24:06

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:48', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '0d7332cd-4a86-4487-bdcb-d4602f1f31ca'	System	10 Aug 2020 21:29:20
User entered 'None (0)'	System	10 Aug 2020 21:29:20

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:51', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '0d7332cd-4a86-4487-bdcb-d4602f1f31ca'	System	10 Aug 2020 21:29:20
User entered 'None (0)'	System	10 Aug 2020 21:29:20

FDA-CBER-2022-1614-0428968

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:54', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '0d7332cd-4a86-4487-bdcb-d4602f1f31ca'	System	10 Aug 2020 21:29:20
User entered 'None (0)'	System	10 Aug 2020 21:29:20

FDA-CBER-2022-1614-0428969

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:28:57', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '0d7332cd-4a86-4487-bdcb-d4602f1f31ca'	System	10 Aug 2020 21:29:20
User entered 'None (0)'	System	10 Aug 2020 21:29:20

FDA-CBER-2022-1614-0428970

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:29:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '0d7332cd-4a86-4487-bdcb-d4602f1f31ca'	System	10 Aug 2020 21:29:20
User entered 'None (0)'	System	10 Aug 2020 21:29:20

FDA-CBER-2022-1614-0428971

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:29:02', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '0d7332cd-4a86-4487-bdcb-d4602f1f31ca'	System	10 Aug 2020 21:29:20
User entered 'None (0)'	System	10 Aug 2020 21:29:20

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:29:14', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '0d7332cd-4a86-4487-bdcb-d4602f1f31ca'	System	10 Aug 2020 21:29:20
User entered 'No (N)'	System	10 Aug 2020 21:29:20

FDA-CBER-2022-1614-0428973

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-10T17:29:18', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '0d7332cd-4a86-4487-bdcb-d4602f1f31ca'	System	10 Aug 2020 21:29:20
User entered '10 Aug 2020 17:29'	System	10 Aug 2020 21:29:20

FDA-CBER-2022-1614-0428974

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428975

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428976

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 6'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428977

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:03:05', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '03da70e4-8960-49e7-999e-dbe0eff4d700'	System	11 Aug 2020 23:03:37
User entered 'None (0)'	System	11 Aug 2020 23:03:37

FDA-CBER-2022-1614-0428978

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:03:09', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '03da70e4-8960-49e7-999e-dbe0eff4d700'	System	11 Aug 2020 23:03:37
User entered 'None (0)'	System	11 Aug 2020 23:03:37

FDA-CBER-2022-1614-0428979

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:03:12', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '03da70e4-8960-49e7-999e-dbe0eff4d700'	System	11 Aug 2020 23:03:37
User entered 'None (0)'	System	11 Aug 2020 23:03:37

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:03:16', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '03da70e4-8960-49e7-999e-dbe0eff4d700'	System	11 Aug 2020 23:03:37
User entered 'None (0)'	System	11 Aug 2020 23:03:37

FDA-CBER-2022-1614-0428981

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:03:19', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '03da70e4-8960-49e7-999e-dbe0eff4d700'	System	11 Aug 2020 23:03:37
User entered 'None (0)'	System	11 Aug 2020 23:03:37

FDA-CBER-2022-1614-0428982

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:03:22', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '03da70e4-8960-49e7-999e-dbe0eff4d700'	System	11 Aug 2020 23:03:37
User entered 'None (0)'	System	11 Aug 2020 23:03:37

FDA-CBER-2022-1614-0428983

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:03:26', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '03da70e4-8960-49e7-999e-dbe0eff4d700'	System	11 Aug 2020 23:03:37
User entered 'No (N)'	System	11 Aug 2020 23:03:37

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-11T19:03:33', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '03da70e4-8960-49e7-999e-dbe0eff4d700'	System	11 Aug 2020 23:03:37
User entered '11 Aug 2020 19:03'	System	11 Aug 2020 23:03:37

FDA-CBER-2022-1614-0428985

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428986

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428987

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 7'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428988

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:20:11', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '477db432-dbaa-4ac7-9569-5cc80e990175'	System	12 Aug 2020 22:20:38
User entered 'None (0)'	System	12 Aug 2020 22:20:38

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:20:15', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '477db432-dbaa-4ac7-9569-5cc80e990175'	System	12 Aug 2020 22:20:38
User entered 'None (0)'	System	12 Aug 2020 22:20:38

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:20:18', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '477db432-dbaa-4ac7-9569-5cc80e990175'	System	12 Aug 2020 22:20:38
User entered 'None (0)'	System	12 Aug 2020 22:20:38

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:20:22', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '477db432-dbaa-4ac7-9569-5cc80e990175'	System	12 Aug 2020 22:20:38
User entered 'None (0)'	System	12 Aug 2020 22:20:38

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:20:25', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '477db432-dbaa-4ac7-9569-5cc80e990175'	System	12 Aug 2020 22:20:38
User entered 'None (0)'	System	12 Aug 2020 22:20:38

FDA-CBER-2022-1614-0428993

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:20:28', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '477db432-dbaa-4ac7-9569-5cc80e990175'	System	12 Aug 2020 22:20:38
User entered 'None (0)'	System	12 Aug 2020 22:20:38

FDA-CBER-2022-1614-0428994

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:20:32', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '477db432-dbaa-4ac7-9569-5cc80e990175'	System	12 Aug 2020 22:20:38
User entered 'No (N)'	System	12 Aug 2020 22:20:38

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-08-12T18:20:36', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '477db432-dbaa-4ac7-9569-5cc80e990175'	System	12 Aug 2020 22:20:38
User entered '12 Aug 2020 18:20'	System	12 Aug 2020 22:20:38

FDA-CBER-2022-1614-0428996

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428997

US3202036
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0428998

US3202036
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:13:28

FDA-CBER-2022-1614-0428999

US3202036
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '13 Aug 2020'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:13:28

US3202036
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Contact Made (CONTACT MADE)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:13:28

FDA-CBER-2022-1614-0429001

US3202036
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:13:28

FDA-CBER-2022-1614-0429002

US3202036
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	31 Aug 2020 16:33:23

US3202036
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '1'	System	31 Aug 2020 16:33:23

FDA-CBER-2022-1614-0429004

US3202036
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	31 Aug 2020 16:33:49

US3202036
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:48:15
User entered '20 Aug 2020' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:07:56
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 13:09:46
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Pt insisted his call be 2 days earlier' (Site from System).	zackery harmon (b) (4) (b) (4)	31 Aug 2020 16:37:54
User entered '26 Aug 2020' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	31 Aug 2020 16:33:56
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	31 Aug 2020 16:33:49
User entered '15 Aug 2020'	zackery harmon (b) (4) (b) (4)	31 Aug 2020 16:33:49

US3202036
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Contact Made (CONTACT MADE)'	zackery harmon (b) (4) (b) (4)	31 Aug 2020 16:33:49

US3202036
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	31 Aug 2020 16:33:49

FDA-CBER-2022-1614-0429008

US3202036
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	31 Aug 2020 16:38:50

US3202036
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '1'	System	31 Aug 2020 16:38:50

US3202036
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:05:30

FDA-CBER-2022-1614-0429011

US3202036
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Oct 2020 20:07:46
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	16 Oct 2020 20:07:46
User entered '27 Aug 2020' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:07:46
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Oct 2020 20:05:30
User entered '20 Aug 2020'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:05:30

US3202036
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Contact Not Made (CONTACT NOT MADE)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:05:30

US3202036
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Attempts x3 LVM'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:05:30

FDA-CBER-2022-1614-0429014

US3202036
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 18:39:03

US3202036
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '1'	System	03 Sep 2020 18:39:03

US3202036
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:16:47

US3202036
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '3 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:16:47

FDA-CBER-2022-1614-0429018

US3202036
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:16:47

FDA-CBER-2022-1614-0429019

US3202036
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'VISIT2'	System	04 Sep 2020 18:16:47

FDA-CBER-2022-1614-0429020

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429021

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429022

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '03 Sep 2020'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '12:57'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429024

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '03 Sep 2020 12:57'	System	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429025

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '36.1' C	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429028

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '58'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429029

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'bpm'	System	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429030

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '14'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429031

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'breaths/min'	System	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429032

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '135'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'mmHg'	System	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429034

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '79'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'mmHg'	System	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429036

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429037

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '03 Sep 2020'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '15:03'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '03 Sep 2020 15:03'	System	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429041

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '36.5' C	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '63'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'bpm'	System	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429046

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '16'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429047

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'breaths/min'	System	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429048

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '131'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'mmHg'	System	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429050

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '74'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:15:02

US3202036
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'mmHg'	System	03 Oct 2020 15:15:02

FDA-CBER-2022-1614-0429052

US3202036
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:20
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:16:35

US3202036
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:20
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:16:35

US3202036
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 18:39:30

US3202036
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 18:39:30

US3202036
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
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)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 18:39:30

US3202036
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429058

US3202036
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '3 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 18:39:30

US3202036
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '13:50'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 18:39:30

US3202036
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '3 Sep 2020 13:50'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429061

US3202036
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 18:39:30

US3202036
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'ONCE'	System	03 Sep 2020 18:39:30

US3202036
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:20
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 18:39:30

US3202036
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:17:10

US3202036
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 23:01:21
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'DCF for correct visit submitted to PPD Central lab on date of collection--EDC visit name is correct. Kit supply issues necessitated use of Unscheduled kit for this visit.' (Site from DM).	Erica Osmundsen (b) (4)	19 Oct 2020 14:53:29
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:20:32
User entered '3 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:17:10

FDA-CBER-2022-1614-0429066

US3202036
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '13:25'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:17:10

US3202036
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '3 Sep 2020 13:25'	System	04 Sep 2020 18:17:10

FDA-CBER-2022-1614-0429068

US3202036
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 15:40:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 11:09:55
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'DCF reported, date here is accurate ' (Site from DM).	zackery harmon (b) (4) (b) (4)	19 Oct 2020 19:54:53
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 12:30:55
User entered '3 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:17:25

US3202036
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:40:20
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:17:25

FDA-CBER-2022-1614-0429070

US3202036
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:40:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:17:25

FDA-CBER-2022-1614-0429071

US3202036
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:40:20
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '13:11'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:17:25

US3202036
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:40:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '3 Sep 2020 13:11'	System	04 Sep 2020 18:17:25

US3202036
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:40:20
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:17:25

FDA-CBER-2022-1614-0429074

US3202036
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:40:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:17:25

US3202036
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:40:20
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	04 Sep 2020 18:17:25

US3202036
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:40:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered empty.	System	04 Sep 2020 18:17:25

US3202036
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 18:39:35

US3202036
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '1'	System	03 Sep 2020 18:39:35

FDA-CBER-2022-1614-0429079

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:03:47', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'efc02331-4664-4d17-894d-fdc562d4272a'	System	03 Sep 2020 19:04:14
User entered 'Yes (Y)'	System	03 Sep 2020 19:04:14

FDA-CBER-2022-1614-0429081

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:03:59', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'efc02331-4664-4d17-894d-fdc562d4272a'	System	03 Sep 2020 19:04:14
User entered '97.7'	System	03 Sep 2020 19:04:14

FDA-CBER-2022-1614-0429082

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:04:04', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'efc02331-4664-4d17-894d-fdc562d4272a'	System	03 Sep 2020 19:04:14
User entered 'No (N)'	System	03 Sep 2020 19:04:14

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:04:11', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'efc02331-4664-4d17-894d-fdc562d4272a'	System	03 Sep 2020 19:04:14
User entered '03 Sep 2020 15:04'	System	03 Sep 2020 19:04:14

FDA-CBER-2022-1614-0429084

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '03 Sep 2020 14:10'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429085

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '03 Sep 2020 16:40'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429086

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:33:22', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a019c5dd-e041-4fca-9c3c-4a50451d8cb5'	System	04 Sep 2020 01:33:46
User entered 'Yes (Y)'	System	04 Sep 2020 01:33:46

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:33:32', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a019c5dd-e041-4fca-9c3c-4a50451d8cb5'	System	04 Sep 2020 01:33:46
User entered '97.5'	System	04 Sep 2020 01:33:46

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:33:37', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a019c5dd-e041-4fca-9c3c-4a50451d8cb5'	System	04 Sep 2020 01:33:46
User entered 'No (N)'	System	04 Sep 2020 01:33:46

FDA-CBER-2022-1614-0429090

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:33:45', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a019c5dd-e041-4fca-9c3c-4a50451d8cb5'	System	04 Sep 2020 01:33:46
User entered '03 Sep 2020 21:33'	System	04 Sep 2020 01:33:46

FDA-CBER-2022-1614-0429091

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '03 Sep 2020 17:35'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429092

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429093

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 2'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:57:15', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '346116e9-5753-4205-8a27-e37fd6f9ae0c'	System	05 Sep 2020 01:57:43
User entered 'Yes (Y)'	System	05 Sep 2020 01:57:43

FDA-CBER-2022-1614-0429095

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:57:23', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '346116e9-5753-4205-8a27-e37fd6f9ae0c'	System	05 Sep 2020 01:57:43
User entered '98.2'	System	05 Sep 2020 01:57:43

FDA-CBER-2022-1614-0429096

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:57:29', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '346116e9-5753-4205-8a27-e37fd6f9ae0c'	System	05 Sep 2020 01:57:43
User entered 'No (N)'	System	05 Sep 2020 01:57:43

FDA-CBER-2022-1614-0429097

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:57:41', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '346116e9-5753-4205-8a27-e37fd6f9ae0c'	System	05 Sep 2020 01:57:43
User entered '04 Sep 2020 21:57'	System	05 Sep 2020 01:57:43

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429099

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 3'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:39:09', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8acc511b-bdc8-40ee-8b48-6dc680890f47'	System	05 Sep 2020 23:40:18
User entered 'Yes (Y)'	System	05 Sep 2020 23:40:18

FDA-CBER-2022-1614-0429102

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:40:08', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8acc511b-bdc8-40ee-8b48-6dc680890f47'	System	05 Sep 2020 23:40:18
User entered '97.1'	System	05 Sep 2020 23:40:18

FDA-CBER-2022-1614-0429103

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:40:12', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8acc511b-bdc8-40ee-8b48-6dc680890f47'	System	05 Sep 2020 23:40:18
User entered 'No (N)'	System	05 Sep 2020 23:40:18

FDA-CBER-2022-1614-0429104

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:40:17', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8acc511b-bdc8-40ee-8b48-6dc680890f47'	System	05 Sep 2020 23:40:18
User entered '05 Sep 2020 19:40'	System	05 Sep 2020 23:40:18

FDA-CBER-2022-1614-0429105

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429106

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429107

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 4'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:01:23', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '96e52281-ea92-43d9-8d81-0b08d72d885d'	System	06 Sep 2020 22:01:44
User entered 'Yes (Y)'	System	06 Sep 2020 22:01:44

FDA-CBER-2022-1614-0429109

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:01:31', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '96e52281-ea92-43d9-8d81-0b08d72d885d'	System	06 Sep 2020 22:01:44
User entered '98.0'	System	06 Sep 2020 22:01:44

FDA-CBER-2022-1614-0429110

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:01:35', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '96e52281-ea92-43d9-8d81-0b08d72d885d'	System	06 Sep 2020 22:01:44
User entered 'No (N)'	System	06 Sep 2020 22:01:44

FDA-CBER-2022-1614-0429111

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:01:41', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '96e52281-ea92-43d9-8d81-0b08d72d885d'	System	06 Sep 2020 22:01:44
User entered '06 Sep 2020 18:01'	System	06 Sep 2020 22:01:44

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429113

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429114

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 5'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:15:45', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '151012bb-acab-4433-8cd0-1c6599a77ee5'	System	07 Sep 2020 23:16:07
User entered 'Yes (Y)'	System	07 Sep 2020 23:16:07

FDA-CBER-2022-1614-0429116

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:15:53', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '151012bb-acab-4433-8cd0-1c6599a77ee5'	System	07 Sep 2020 23:16:07
User entered '97.0'	System	07 Sep 2020 23:16:07

FDA-CBER-2022-1614-0429117

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:15:58', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '151012bb-acab-4433-8cd0-1c6599a77ee5'	System	07 Sep 2020 23:16:07
User entered 'No (N)'	System	07 Sep 2020 23:16:07

FDA-CBER-2022-1614-0429118

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:16:03', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '151012bb-acab-4433-8cd0-1c6599a77ee5'	System	07 Sep 2020 23:16:07
User entered '07 Sep 2020 19:16'	System	07 Sep 2020 23:16:07

FDA-CBER-2022-1614-0429119

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429120

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429121

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 6'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429122

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:47:26', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'b3d5f9e3-a50b-4c80-b361-ef1e3b0c8a02'	System	08 Sep 2020 16:47:44
User entered 'Yes (Y)'	System	08 Sep 2020 16:47:44

FDA-CBER-2022-1614-0429123

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:47:33', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'b3d5f9e3-a50b-4c80-b361-ef1e3b0c8a02'	System	08 Sep 2020 16:47:44
User entered '98.2'	System	08 Sep 2020 16:47:44

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:47:37', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'b3d5f9e3-a50b-4c80-b361-ef1e3b0c8a02'	System	08 Sep 2020 16:47:44
User entered 'No (N)'	System	08 Sep 2020 16:47:44

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:47:39', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'b3d5f9e3-a50b-4c80-b361-ef1e3b0c8a02'	System	08 Sep 2020 16:47:44
User entered '08 Sep 2020 12:47'	System	08 Sep 2020 16:47:44

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429127

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429128

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 7'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429129

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:18:56', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '60f27ae2-d7f9-4a03-bb84-979860f42bf8'	System	09 Sep 2020 16:20:42
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:42

FDA-CBER-2022-1614-0429130

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:20:23', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '60f27ae2-d7f9-4a03-bb84-979860f42bf8'	System	09 Sep 2020 16:20:42
User entered '98.5'	System	09 Sep 2020 16:20:42

FDA-CBER-2022-1614-0429131

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:20:29', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '60f27ae2-d7f9-4a03-bb84-979860f42bf8'	System	09 Sep 2020 16:20:42
User entered 'No (N)'	System	09 Sep 2020 16:20:42

FDA-CBER-2022-1614-0429132

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:20:39', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '60f27ae2-d7f9-4a03-bb84-979860f42bf8'	System	09 Sep 2020 16:20:42
User entered '09 Sep 2020 12:20'	System	09 Sep 2020 16:20:42

FDA-CBER-2022-1614-0429133

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429134

US3202036
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429135

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429136

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:04:23', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7bcd5a35-bf7a-4a43-b2b6-47f10c94a68b'	System	03 Sep 2020 19:04:48
User entered 'None (1)'	System	03 Sep 2020 19:04:48

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:04:27', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7bcd5a35-bf7a-4a43-b2b6-47f10c94a68b'	System	03 Sep 2020 19:04:48
User entered 'No (N)'	System	03 Sep 2020 19:04:48

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:04:30', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7bcd5a35-bf7a-4a43-b2b6-47f10c94a68b'	System	03 Sep 2020 19:04:48
User entered 'No (N)'	System	03 Sep 2020 19:04:48

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:04:38', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7bcd5a35-bf7a-4a43-b2b6-47f10c94a68b'	System	03 Sep 2020 19:04:48
User entered 'None (1)'	System	03 Sep 2020 19:04:48

FDA-CBER-2022-1614-0429140

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:04:45', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7bcd5a35-bf7a-4a43-b2b6-47f10c94a68b'	System	03 Sep 2020 19:04:48
User entered '03 Sep 2020 15:04'	System	03 Sep 2020 19:04:48

FDA-CBER-2022-1614-0429141

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '03 Sep 2020 14:10'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429142

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '03 Sep 2020 16:40'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429143

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429144

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:33:59', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9827e6c2-1143-4fd9-a558-563b40d1dfc0'	System	04 Sep 2020 01:34:19
User entered 'None (1)'	System	04 Sep 2020 01:34:19

FDA-CBER-2022-1614-0429145

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:03', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9827e6c2-1143-4fd9-a558-563b40d1dfc0'	System	04 Sep 2020 01:34:19
User entered 'No (N)'	System	04 Sep 2020 01:34:19

FDA-CBER-2022-1614-0429146

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:07', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9827e6c2-1143-4fd9-a558-563b40d1dfc0'	System	04 Sep 2020 01:34:19
User entered 'No (N)'	System	04 Sep 2020 01:34:19

FDA-CBER-2022-1614-0429147

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:12', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9827e6c2-1143-4fd9-a558-563b40d1dfc0'	System	04 Sep 2020 01:34:19
User entered 'None (1)'	System	04 Sep 2020 01:34:19

FDA-CBER-2022-1614-0429148

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:17', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9827e6c2-1143-4fd9-a558-563b40d1dfc0'	System	04 Sep 2020 01:34:19
User entered '03 Sep 2020 21:34'	System	04 Sep 2020 01:34:19

FDA-CBER-2022-1614-0429149

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '03 Sep 2020 17:35'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429150

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429151

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 2'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429152

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:58:05', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6b33e827-b28c-4511-aa5d-0cce7be1f0bc'	System	05 Sep 2020 01:58:40
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 01:58:40

FDA-CBER-2022-1614-0429153

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:58:19', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6b33e827-b28c-4511-aa5d-0cce7be1f0bc'	System	05 Sep 2020 01:58:40
User entered 'No (N)'	System	05 Sep 2020 01:58:40

FDA-CBER-2022-1614-0429154

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:58:24', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6b33e827-b28c-4511-aa5d-0cce7be1f0bc'	System	05 Sep 2020 01:58:40
User entered 'No (N)'	System	05 Sep 2020 01:58:40

FDA-CBER-2022-1614-0429155

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:58:32', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6b33e827-b28c-4511-aa5d-0cce7be1f0bc'	System	05 Sep 2020 01:58:40
User entered 'None (1)'	System	05 Sep 2020 01:58:40

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:58:38', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6b33e827-b28c-4511-aa5d-0cce7be1f0bc'	System	05 Sep 2020 01:58:40
User entered '04 Sep 2020 21:58'	System	05 Sep 2020 01:58:40

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

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US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429159

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 3'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:40:41', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6deb675b-9467-43ab-948a-b1bfcfa224c1'	System	05 Sep 2020 23:41:08
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 23:41:08

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US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:40:45', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6deb675b-9467-43ab-948a-b1bfcfa224c1'	System	05 Sep 2020 23:41:08
User entered 'No (N)'	System	05 Sep 2020 23:41:08

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:40:49', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6deb675b-9467-43ab-948a-b1bfcfa224c1'	System	05 Sep 2020 23:41:08
User entered 'No (N)'	System	05 Sep 2020 23:41:08

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:40:59', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6deb675b-9467-43ab-948a-b1bfcfa224c1'	System	05 Sep 2020 23:41:08
User entered 'None (1)'	System	05 Sep 2020 23:41:08

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:41:06', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6deb675b-9467-43ab-948a-b1bfcfa224c1'	System	05 Sep 2020 23:41:08
User entered '05 Sep 2020 19:41'	System	05 Sep 2020 23:41:08

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US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429166

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 4'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:01:48', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'cd05b041-6318-4dee-90dd-33141c36eb60'	System	06 Sep 2020 22:02:08
User entered 'None (1)'	System	06 Sep 2020 22:02:08

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:01:51', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'cd05b041-6318-4dee-90dd-33141c36eb60'	System	06 Sep 2020 22:02:08
User entered 'No (N)'	System	06 Sep 2020 22:02:08

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:01:55', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'cd05b041-6318-4dee-90dd-33141c36eb60'	System	06 Sep 2020 22:02:08
User entered 'No (N)'	System	06 Sep 2020 22:02:08

FDA-CBER-2022-1614-0429171

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:02:01', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'cd05b041-6318-4dee-90dd-33141c36eb60'	System	06 Sep 2020 22:02:08
User entered 'None (1)'	System	06 Sep 2020 22:02:08

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:02:06', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'cd05b041-6318-4dee-90dd-33141c36eb60'	System	06 Sep 2020 22:02:08
User entered '06 Sep 2020 18:02'	System	06 Sep 2020 22:02:08

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US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429174

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429175

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 5'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:16:11', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3e0e4940-99bd-4c29-bf61-cdf14fd3f984'	System	07 Sep 2020 23:16:38
User entered 'None (1)'	System	07 Sep 2020 23:16:38

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:16:18', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3e0e4940-99bd-4c29-bf61-cdf14fd3f984'	System	07 Sep 2020 23:16:38
User entered 'No (N)'	System	07 Sep 2020 23:16:38

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:16:24', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3e0e4940-99bd-4c29-bf61-cdf14fd3f984'	System	07 Sep 2020 23:16:38
User entered 'No (N)'	System	07 Sep 2020 23:16:38

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US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:16:28', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3e0e4940-99bd-4c29-bf61-cdf14fd3f984'	System	07 Sep 2020 23:16:38
User entered 'None (1)'	System	07 Sep 2020 23:16:38

FDA-CBER-2022-1614-0429180

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:16:35', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3e0e4940-99bd-4c29-bf61-cdf14fd3f984'	System	07 Sep 2020 23:16:38
User entered '07 Sep 2020 19:16'	System	07 Sep 2020 23:16:38

FDA-CBER-2022-1614-0429181

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429182

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429183

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 6'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:47:43', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8022fcaa-dbec-4f80-a108-c6a77849ba8b'	System	08 Sep 2020 16:48:00
User entered 'None (1)'	System	08 Sep 2020 16:48:00

FDA-CBER-2022-1614-0429185

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:47:47', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8022fcaa-dbec-4f80-a108-c6a77849ba8b'	System	08 Sep 2020 16:48:00
User entered 'No (N)'	System	08 Sep 2020 16:48:00

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:47:50', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8022fcaa-dbec-4f80-a108-c6a77849ba8b'	System	08 Sep 2020 16:48:00
User entered 'No (N)'	System	08 Sep 2020 16:48:00

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:47:53', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8022fcaa-dbec-4f80-a108-c6a77849ba8b'	System	08 Sep 2020 16:48:00
User entered 'None (1)'	System	08 Sep 2020 16:48:00

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:47:56', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8022fcaa-dbec-4f80-a108-c6a77849ba8b'	System	08 Sep 2020 16:48:00
User entered '08 Sep 2020 12:47'	System	08 Sep 2020 16:48:00

FDA-CBER-2022-1614-0429189

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429190

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429191

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 7'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:20:50', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9ed3b05e-d74b-4bbe-a2e9-140450e6b132'	System	09 Sep 2020 16:21:17
User entered 'None (1)'	System	09 Sep 2020 16:21:17

FDA-CBER-2022-1614-0429193

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:20:57', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9ed3b05e-d74b-4bbe-a2e9-140450e6b132'	System	09 Sep 2020 16:21:17
User entered 'No (N)'	System	09 Sep 2020 16:21:17

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:21:01', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9ed3b05e-d74b-4bbe-a2e9-140450e6b132'	System	09 Sep 2020 16:21:17
User entered 'No (N)'	System	09 Sep 2020 16:21:17

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:21:04', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9ed3b05e-d74b-4bbe-a2e9-140450e6b132'	System	09 Sep 2020 16:21:17
User entered 'None (1)'	System	09 Sep 2020 16:21:17

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:21:13', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9ed3b05e-d74b-4bbe-a2e9-140450e6b132'	System	09 Sep 2020 16:21:17
User entered '09 Sep 2020 12:21'	System	09 Sep 2020 16:21:17

FDA-CBER-2022-1614-0429197

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429198

US3202036
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429199

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:04:51', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '148fce3b-a3ae-4f64-8e2e-db7cf9a31110'	System	03 Sep 2020 19:05:27
User entered 'None (0)'	System	03 Sep 2020 19:05:27

FDA-CBER-2022-1614-0429201

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:04:55', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '148fce3b-a3ae-4f64-8e2e-db7cf9a31110'	System	03 Sep 2020 19:05:27
User entered 'None (0)'	System	03 Sep 2020 19:05:27

FDA-CBER-2022-1614-0429202

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:04:58', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '148fce3b-a3ae-4f64-8e2e-db7cf9a31110'	System	03 Sep 2020 19:05:27
User entered 'None (0)'	System	03 Sep 2020 19:05:27

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:05:02', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '148fce3b-a3ae-4f64-8e2e-db7cf9a31110'	System	03 Sep 2020 19:05:27
User entered 'None (0)'	System	03 Sep 2020 19:05:27

FDA-CBER-2022-1614-0429204

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:05:05', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '148fce3b-a3ae-4f64-8e2e-db7cf9a31110'	System	03 Sep 2020 19:05:27
User entered 'None (0)'	System	03 Sep 2020 19:05:27

FDA-CBER-2022-1614-0429205

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:05:08', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '148fce3b-a3ae-4f64-8e2e-db7cf9a31110'	System	03 Sep 2020 19:05:27
User entered 'None (0)'	System	03 Sep 2020 19:05:27

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:05:19', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '148fce3b-a3ae-4f64-8e2e-db7cf9a31110'	System	03 Sep 2020 19:05:27
User entered 'No (N)'	System	03 Sep 2020 19:05:27

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T15:05:25', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '148fce3b-a3ae-4f64-8e2e-db7cf9a31110'	System	03 Sep 2020 19:05:27
User entered '03 Sep 2020 15:05'	System	03 Sep 2020 19:05:27

FDA-CBER-2022-1614-0429208

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '03 Sep 2020 14:10'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429209

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '03 Sep 2020 16:40'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429210

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:24', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a53e43f9-43b1-444b-a957-cbe5c638d63d'	System	04 Sep 2020 01:34:54
User entered 'None (0)'	System	04 Sep 2020 01:34:54

FDA-CBER-2022-1614-0429212

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:27', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a53e43f9-43b1-444b-a957-cbe5c638d63d'	System	04 Sep 2020 01:34:54
User entered 'None (0)'	System	04 Sep 2020 01:34:54

FDA-CBER-2022-1614-0429213

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:32', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a53e43f9-43b1-444b-a957-cbe5c638d63d'	System	04 Sep 2020 01:34:54
User entered 'None (0)'	System	04 Sep 2020 01:34:54

FDA-CBER-2022-1614-0429214

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:35', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a53e43f9-43b1-444b-a957-cbe5c638d63d'	System	04 Sep 2020 01:34:54
User entered 'None (0)'	System	04 Sep 2020 01:34:54

FDA-CBER-2022-1614-0429215

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:39', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a53e43f9-43b1-444b-a957-cbe5c638d63d'	System	04 Sep 2020 01:34:54
User entered 'None (0)'	System	04 Sep 2020 01:34:54

FDA-CBER-2022-1614-0429216

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:42', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a53e43f9-43b1-444b-a957-cbe5c638d63d'	System	04 Sep 2020 01:34:54
User entered 'None (0)'	System	04 Sep 2020 01:34:54

FDA-CBER-2022-1614-0429217

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:48', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a53e43f9-43b1-444b-a957-cbe5c638d63d'	System	04 Sep 2020 01:34:54
User entered 'No (N)'	System	04 Sep 2020 01:34:54

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-03T21:34:53', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a53e43f9-43b1-444b-a957-cbe5c638d63d'	System	04 Sep 2020 01:34:54
User entered '03 Sep 2020 21:34'	System	04 Sep 2020 01:34:54

FDA-CBER-2022-1614-0429219

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '03 Sep 2020 17:35'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429220

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429221

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 2'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:58:46', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '87e1520d-46eb-46dc-bc97-efa8bbb21ce5'	System	05 Sep 2020 01:59:26
User entered 'None (0)'	System	05 Sep 2020 01:59:26

FDA-CBER-2022-1614-0429223

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:58:50', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '87e1520d-46eb-46dc-bc97-efa8bbb21ce5'	System	05 Sep 2020 01:59:26
User entered 'None (0)'	System	05 Sep 2020 01:59:26

FDA-CBER-2022-1614-0429224

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:58:54', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '87e1520d-46eb-46dc-bc97-efa8bbb21ce5'	System	05 Sep 2020 01:59:26
User entered 'None (0)'	System	05 Sep 2020 01:59:26

FDA-CBER-2022-1614-0429225

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:58:57', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '87e1520d-46eb-46dc-bc97-efa8bbb21ce5'	System	05 Sep 2020 01:59:26
User entered 'None (0)'	System	05 Sep 2020 01:59:26

FDA-CBER-2022-1614-0429226

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:59:01', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '87e1520d-46eb-46dc-bc97-efa8bbb21ce5'	System	05 Sep 2020 01:59:26
User entered 'None (0)'	System	05 Sep 2020 01:59:26

FDA-CBER-2022-1614-0429227

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:59:04', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '87e1520d-46eb-46dc-bc97-efa8bbb21ce5'	System	05 Sep 2020 01:59:26
User entered 'None (0)'	System	05 Sep 2020 01:59:26

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:59:17', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '87e1520d-46eb-46dc-bc97-efa8bbb21ce5'	System	05 Sep 2020 01:59:26
User entered 'No (N)'	System	05 Sep 2020 01:59:26

FDA-CBER-2022-1614-0429229

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-04T21:59:23', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '87e1520d-46eb-46dc-bc97-efa8bbb21ce5'	System	05 Sep 2020 01:59:26
User entered '04 Sep 2020 21:59'	System	05 Sep 2020 01:59:26

FDA-CBER-2022-1614-0429230

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429231

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429232

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 3'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:41:15', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2f2efc13-ba25-4b3a-a5f7-bdbf77cbe824'	System	05 Sep 2020 23:41:49
User entered 'None (0)'	System	05 Sep 2020 23:41:49

FDA-CBER-2022-1614-0429234

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:41:20', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2f2efc13-ba25-4b3a-a5f7-bdbf77cbe824'	System	05 Sep 2020 23:41:49
User entered 'None (0)'	System	05 Sep 2020 23:41:49

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:41:25', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2f2efc13-ba25-4b3a-a5f7-bdbf77cbe824'	System	05 Sep 2020 23:41:49
User entered 'None (0)'	System	05 Sep 2020 23:41:49

FDA-CBER-2022-1614-0429236

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:41:28', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2f2efc13-ba25-4b3a-a5f7-bdbf77cbe824'	System	05 Sep 2020 23:41:49
User entered 'None (0)'	System	05 Sep 2020 23:41:49

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:41:32', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2f2efc13-ba25-4b3a-a5f7-bdbf77cbe824'	System	05 Sep 2020 23:41:49
User entered 'None (0)'	System	05 Sep 2020 23:41:49

FDA-CBER-2022-1614-0429238

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:41:34', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2f2efc13-ba25-4b3a-a5f7-bdbf77cbe824'	System	05 Sep 2020 23:41:49
User entered 'None (0)'	System	05 Sep 2020 23:41:49

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:41:42', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2f2efc13-ba25-4b3a-a5f7-bdbf77cbe824'	System	05 Sep 2020 23:41:49
User entered 'No (N)'	System	05 Sep 2020 23:41:49

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-05T19:41:47', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2f2efc13-ba25-4b3a-a5f7-bdbf77cbe824'	System	05 Sep 2020 23:41:49
User entered '05 Sep 2020 19:41'	System	05 Sep 2020 23:41:49

FDA-CBER-2022-1614-0429241

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429242

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429243

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 4'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429244

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:02:12', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'e244d2d5-62a6-4857-92c2-7a4c782ce2a1'	System	06 Sep 2020 22:02:37
User entered 'None (0)'	System	06 Sep 2020 22:02:37

FDA-CBER-2022-1614-0429245

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:02:15', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'e244d2d5-62a6-4857-92c2-7a4c782ce2a1'	System	06 Sep 2020 22:02:37
User entered 'None (0)'	System	06 Sep 2020 22:02:37

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:02:18', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'e244d2d5-62a6-4857-92c2-7a4c782ce2a1'	System	06 Sep 2020 22:02:37
User entered 'None (0)'	System	06 Sep 2020 22:02:37

FDA-CBER-2022-1614-0429247

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:02:21', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'e244d2d5-62a6-4857-92c2-7a4c782ce2a1'	System	06 Sep 2020 22:02:37
User entered 'None (0)'	System	06 Sep 2020 22:02:37

FDA-CBER-2022-1614-0429248

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:02:24', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'e244d2d5-62a6-4857-92c2-7a4c782ce2a1'	System	06 Sep 2020 22:02:37
User entered 'None (0)'	System	06 Sep 2020 22:02:37

FDA-CBER-2022-1614-0429249

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:02:27', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'e244d2d5-62a6-4857-92c2-7a4c782ce2a1'	System	06 Sep 2020 22:02:37
User entered 'None (0)'	System	06 Sep 2020 22:02:37

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:02:32', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'e244d2d5-62a6-4857-92c2-7a4c782ce2a1'	System	06 Sep 2020 22:02:37
User entered 'No (N)'	System	06 Sep 2020 22:02:37

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-06T18:02:35', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'e244d2d5-62a6-4857-92c2-7a4c782ce2a1'	System	06 Sep 2020 22:02:37
User entered '06 Sep 2020 18:02'	System	06 Sep 2020 22:02:37

FDA-CBER-2022-1614-0429252

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429253

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429254

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 5'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:16:45', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6c53392-e471-4fbc-8cc7-99692cad2cd4'	System	07 Sep 2020 23:17:38
User entered 'None (0)'	System	07 Sep 2020 23:17:38

FDA-CBER-2022-1614-0429256

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:16:49', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6c53392-e471-4fbc-8cc7-99692cad2cd4'	System	07 Sep 2020 23:17:38
User entered 'None (0)'	System	07 Sep 2020 23:17:38

FDA-CBER-2022-1614-0429257

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:16:55', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6c53392-e471-4fbc-8cc7-99692cad2cd4'	System	07 Sep 2020 23:17:38
User entered 'None (0)'	System	07 Sep 2020 23:17:38

FDA-CBER-2022-1614-0429258

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:17:02', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6c53392-e471-4fbc-8cc7-99692cad2cd4'	System	07 Sep 2020 23:17:38
User entered 'None (0)'	System	07 Sep 2020 23:17:38

FDA-CBER-2022-1614-0429259

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:17:20', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6c53392-e471-4fbc-8cc7-99692cad2cd4'	System	07 Sep 2020 23:17:38
User entered 'None (0)'	System	07 Sep 2020 23:17:38

FDA-CBER-2022-1614-0429260

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:17:23', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6c53392-e471-4fbc-8cc7-99692cad2cd4'	System	07 Sep 2020 23:17:38
User entered 'None (0)'	System	07 Sep 2020 23:17:38

FDA-CBER-2022-1614-0429261

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:17:27', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6c53392-e471-4fbc-8cc7-99692cad2cd4'	System	07 Sep 2020 23:17:38
User entered 'No (N)'	System	07 Sep 2020 23:17:38

FDA-CBER-2022-1614-0429262

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-07T19:17:35', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'd6c53392-e471-4fbc-8cc7-99692cad2cd4'	System	07 Sep 2020 23:17:38
User entered '07 Sep 2020 19:17'	System	07 Sep 2020 23:17:38

FDA-CBER-2022-1614-0429263

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429264

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429265

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 6'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:48:02', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3a4a8056-117c-4ac4-9874-dffdb75c7da5'	System	08 Sep 2020 16:48:25
User entered 'None (0)'	System	08 Sep 2020 16:48:25

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:48:05', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3a4a8056-117c-4ac4-9874-dffdb75c7da5'	System	08 Sep 2020 16:48:25
User entered 'None (0)'	System	08 Sep 2020 16:48:25

FDA-CBER-2022-1614-0429268

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:48:08', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3a4a8056-117c-4ac4-9874-dffdb75c7da5'	System	08 Sep 2020 16:48:25
User entered 'None (0)'	System	08 Sep 2020 16:48:25

FDA-CBER-2022-1614-0429269

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:48:11', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3a4a8056-117c-4ac4-9874-dffdb75c7da5'	System	08 Sep 2020 16:48:25
User entered 'None (0)'	System	08 Sep 2020 16:48:25

FDA-CBER-2022-1614-0429270

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:48:14', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3a4a8056-117c-4ac4-9874-dffdb75c7da5'	System	08 Sep 2020 16:48:25
User entered 'None (0)'	System	08 Sep 2020 16:48:25

FDA-CBER-2022-1614-0429271

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:48:16', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3a4a8056-117c-4ac4-9874-dffdb75c7da5'	System	08 Sep 2020 16:48:25
User entered 'None (0)'	System	08 Sep 2020 16:48:25

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:48:20', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3a4a8056-117c-4ac4-9874-dffdb75c7da5'	System	08 Sep 2020 16:48:25
User entered 'No (N)'	System	08 Sep 2020 16:48:25

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-08T12:48:23', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3a4a8056-117c-4ac4-9874-dffdb75c7da5'	System	08 Sep 2020 16:48:25
User entered '08 Sep 2020 12:48'	System	08 Sep 2020 16:48:25

FDA-CBER-2022-1614-0429274

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429275

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429276

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	03 Sep 2020 18:39:30
User entered 'Day 7'	System	03 Sep 2020 18:39:30

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:21:20', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8c509c72-14bd-4be7-965a-555ff298358a'	System	09 Sep 2020 16:21:53
User entered 'None (0)'	System	09 Sep 2020 16:21:53

FDA-CBER-2022-1614-0429278

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:21:23', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8c509c72-14bd-4be7-965a-555ff298358a'	System	09 Sep 2020 16:21:53
User entered 'None (0)'	System	09 Sep 2020 16:21:53

FDA-CBER-2022-1614-0429279

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:21:26', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8c509c72-14bd-4be7-965a-555ff298358a'	System	09 Sep 2020 16:21:53
User entered 'None (0)'	System	09 Sep 2020 16:21:53

FDA-CBER-2022-1614-0429280

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:21:28', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8c509c72-14bd-4be7-965a-555ff298358a'	System	09 Sep 2020 16:21:53
User entered 'None (0)'	System	09 Sep 2020 16:21:53

FDA-CBER-2022-1614-0429281

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:21:31', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8c509c72-14bd-4be7-965a-555ff298358a'	System	09 Sep 2020 16:21:53
User entered 'None (0)'	System	09 Sep 2020 16:21:53

FDA-CBER-2022-1614-0429282

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:21:34', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8c509c72-14bd-4be7-965a-555ff298358a'	System	09 Sep 2020 16:21:53
User entered 'None (0)'	System	09 Sep 2020 16:21:53

FDA-CBER-2022-1614-0429283

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
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)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:21:45', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8c509c72-14bd-4be7-965a-555ff298358a'	System	09 Sep 2020 16:21:53
User entered 'No (N)'	System	09 Sep 2020 16:21:53

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-09-09T12:21:48', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8c509c72-14bd-4be7-965a-555ff298358a'	System	09 Sep 2020 16:21:53
User entered '09 Sep 2020 12:21'	System	09 Sep 2020 16:21:53

FDA-CBER-2022-1614-0429285

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429286

US3202036
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:39:30

FDA-CBER-2022-1614-0429287

US3202036
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:09:14

FDA-CBER-2022-1614-0429288

US3202036
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '10 Sep 2020'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:09:14

US3202036
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Contact Made (CONTACT MADE)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:09:14

FDA-CBER-2022-1614-0429290

US3202036
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:09:14

FDA-CBER-2022-1614-0429291

US3202036
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 20:26:18

FDA-CBER-2022-1614-0429292

US3202036
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '1'	System	24 Sep 2020 20:26:18

US3202036
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 20:30:23

FDA-CBER-2022-1614-0429294

US3202036
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '17 Sep 2020'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 20:30:23

FDA-CBER-2022-1614-0429295

US3202036
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 20:30:23

FDA-CBER-2022-1614-0429296

US3202036
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'subject did not return call'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 20:30:23

FDA-CBER-2022-1614-0429297

US3202036
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 20:29:55

FDA-CBER-2022-1614-0429298

US3202036
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '1'	System	24 Sep 2020 20:29:55

US3202036
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 20:30:39

US3202036
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '24 Sep 2020'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 20:30:39

FDA-CBER-2022-1614-0429301

US3202036
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 20:30:39

US3202036
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 20:30:39

FDA-CBER-2022-1614-0429303

US3202036
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	24 Sep 2020 20:30:44

FDA-CBER-2022-1614-0429304

US3202036
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '1'	System	24 Sep 2020 20:30:44

US3202036
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:10:57

US3202036
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '01 Oct 2020'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:10:57

FDA-CBER-2022-1614-0429307

US3202036
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Clinic (Clinic)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:10:57

US3202036
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User entered 'VISIT3'	System	16 Oct 2020 20:10:57

FDA-CBER-2022-1614-0429309

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429310

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '01 Oct 2020'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429311

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '12:14'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429312

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User entered '01 Oct 2020 12:14'	System	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429313

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '36.3' C	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429314

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:32

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429316

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '71'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429317

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User entered 'bpm'	System	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429318

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '16'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429319

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User entered 'breaths/min'	System	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429320

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '113'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429321

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User entered 'mmHg'	System	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429322

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '73'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429323

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User entered 'mmHg'	System	16 Oct 2020 20:12:32

FDA-CBER-2022-1614-0429324

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29

FDA-CBER-2022-1614-0429325

US3202036
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29

FDA-CBER-2022-1614-0429326

US3202036
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:20
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:36

US3202036
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:20
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:12:36

FDA-CBER-2022-1614-0429328

US3202036
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:15:20

US3202036
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '01 Oct 2020'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:15:20

FDA-CBER-2022-1614-0429330

US3202036
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered '12:30'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:15:20

FDA-CBER-2022-1614-0429331

US3202036
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:22:29
User entered '01 Oct 2020 12:30'	System	16 Oct 2020 20:15:20

US3202036
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:48:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:15:23

US3202036
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '1'	System	16 Oct 2020 20:15:23

FDA-CBER-2022-1614-0429334

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 64'	System	06 Aug 2020 17:24:06

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429337

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429338

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429339

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429340

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429341

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429345

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429351

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429353

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 17:24:06

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 17:24:06

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 71'	System	06 Aug 2020 17:24:06

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429365

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429373

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429374

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429383

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429388

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 17:24:06

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 17:24:06

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 78'	System	06 Aug 2020 17:24:06

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20

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 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429393

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429394

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429397

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429401

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429407

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429409

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429411

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429412

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429413

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
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)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

FDA-CBER-2022-1614-0429415

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 17:24:06

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:39:50
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 17:24:06

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 92'	System	06 Aug 2020 17:24:06

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-04T10:20:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3efbfbc8-2100-4dad-af90-f061d5090699'	System	04 Nov 2020 15:20:17
User entered 'No (N)'	System	04 Nov 2020 15:20:17

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-04T10:20:08', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3efbfbc8-2100-4dad-af90-f061d5090699'	System	04 Nov 2020 15:20:17
User entered 'No (N)'	System	04 Nov 2020 15:20:17

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-04T10:20:15', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '3efbfbc8-2100-4dad-af90-f061d5090699'	System	04 Nov 2020 15:20:17
User entered '04 Nov 2020 10:20:15'	System	04 Nov 2020 15:20:17

FDA-CBER-2022-1614-0429422

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 17:24:06

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 17:24:06

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 99'	System	06 Aug 2020 17:24:06

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Feb 2021 04:22:25
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 22:06:13
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'went to doctor for check up' (Site from DM).	zackery harmon (b) (4)	02 Dec 2020 17:27:57
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 16:36:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-10T11:48:44', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'efa15d11-ac5f-4512-93b9-6ea5022104e1'	System	10 Nov 2020 16:50:29
User entered 'Yes (Y)'	System	10 Nov 2020 16:50:29

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-10T11:48:57', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'efa15d11-ac5f-4512-93b9-6ea5022104e1'	System	10 Nov 2020 16:50:29
User entered 'Yes (Y)'	System	10 Nov 2020 16:50:29

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-10T11:49:19', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'efa15d11-ac5f-4512-93b9-6ea5022104e1'	System	10 Nov 2020 16:50:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Nov 2020 16:50:29

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-10T11:49:28', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'efa15d11-ac5f-4512-93b9-6ea5022104e1'	System	10 Nov 2020 16:50:29
User entered 'No (N)'	System	10 Nov 2020 16:50:29

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-10T11:49:39', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'efa15d11-ac5f-4512-93b9-6ea5022104e1'	System	10 Nov 2020 16:50:29
User entered 'Yes (Y)'	System	10 Nov 2020 16:50:29

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-10T11:49:49', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'efa15d11-ac5f-4512-93b9-6ea5022104e1'	System	10 Nov 2020 16:50:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Nov 2020 16:50:29

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-10T11:50:16', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'efa15d11-ac5f-4512-93b9-6ea5022104e1'	System	10 Nov 2020 16:50:29
User entered '10 Nov 2020 11:50:16'	System	10 Nov 2020 16:50:29

FDA-CBER-2022-1614-0429432

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0429433

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0429434

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered 'Day 106'	System	06 Aug 2020 17:24:06

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-18T08:45:53', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'ed96ffab-2e35-433b-8cd9-03853c16c587'	System	18 Nov 2020 13:46:58
User entered 'No (N)'	System	18 Nov 2020 13:46:58

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-18T08:46:26', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'ed96ffab-2e35-433b-8cd9-03853c16c587'	System	18 Nov 2020 13:46:58
User entered 'Yes (Y)'	System	18 Nov 2020 13:46:58

US3202036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-18T08:46:36', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'ed96ffab-2e35-433b-8cd9-03853c16c587'	System	18 Nov 2020 13:46:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 13:46:58

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-18T08:46:50', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'ed96ffab-2e35-433b-8cd9-03853c16c587'	System	18 Nov 2020 13:46:58
User entered '18 Nov 2020 08:46:50'	System	18 Nov 2020 13:46:58

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 17:24:06

FDA-CBER-2022-1614-0429440

US3202036
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:22:25
Data entry locked.	System	06 Aug 2020 17:24:06
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 17:24:06

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-22T14:06:21', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '42dc7362-4b60-438b-8c4a-5e81985334a9'	System	22 Nov 2020 19:06:40
User entered 'No (N)'	System	22 Nov 2020 19:06:40

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-22T14:06:30', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '42dc7362-4b60-438b-8c4a-5e81985334a9'	System	22 Nov 2020 19:06:40
User entered 'No (N)'	System	22 Nov 2020 19:06:40

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-22T14:06:38', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '42dc7362-4b60-438b-8c4a-5e81985334a9'	System	22 Nov 2020 19:06:40
User entered '22 Nov 2020 14:06:38'	System	22 Nov 2020 19:06:40

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-28T15:11:21', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2cd0a949-18c0-4f93-aa1b-269ed71ec1c9'	System	28 Nov 2020 20:11:38
User entered 'No (N)'	System	28 Nov 2020 20:11:38

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-28T15:11:29', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2cd0a949-18c0-4f93-aa1b-269ed71ec1c9'	System	28 Nov 2020 20:11:38
User entered 'No (N)'	System	28 Nov 2020 20:11:38

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-11-28T15:11:35', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '2cd0a949-18c0-4f93-aa1b-269ed71ec1c9'	System	28 Nov 2020 20:11:38
User entered '28 Nov 2020 15:11:35'	System	28 Nov 2020 20:11:38

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-12-05T09:09:36', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f93edeae-b242-488e-8af8-dbf1acea9fd5'	System	05 Dec 2020 14:09:55
User entered 'No (N)'	System	05 Dec 2020 14:09:55

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-12-05T09:09:47', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f93edeae-b242-488e-8af8-dbf1acea9fd5'	System	05 Dec 2020 14:09:55
User entered 'No (N)'	System	05 Dec 2020 14:09:55

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-12-05T09:09:53', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'f93edeae-b242-488e-8af8-dbf1acea9fd5'	System	05 Dec 2020 14:09:55
User entered '05 Dec 2020 09:09:53'	System	05 Dec 2020 14:09:55

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-12-14T12:01:45', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '62849526-2257-42c6-b617-2511ee4b41ed'	System	14 Dec 2020 17:02:01
User entered 'No (N)'	System	14 Dec 2020 17:02:01

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-12-14T12:01:50', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '62849526-2257-42c6-b617-2511ee4b41ed'	System	14 Dec 2020 17:02:01
User entered 'No (N)'	System	14 Dec 2020 17:02:01

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-12-14T12:01:56', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '62849526-2257-42c6-b617-2511ee4b41ed'	System	14 Dec 2020 17:02:01
User entered '14 Dec 2020 12:01:56'	System	14 Dec 2020 17:02:01

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-12-28T18:01:14', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '44738623-223d-4eb2-852e-e1d0f0e1f9d0'	System	28 Dec 2020 23:01:28
User entered 'No (N)'	System	28 Dec 2020 23:01:28

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-12-28T18:01:19', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '44738623-223d-4eb2-852e-e1d0f0e1f9d0'	System	28 Dec 2020 23:01:28
User entered 'No (N)'	System	28 Dec 2020 23:01:28

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2020-12-28T18:01:24', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '44738623-223d-4eb2-852e-e1d0f0e1f9d0'	System	28 Dec 2020 23:01:28
User entered '28 Dec 2020 18:01:24'	System	28 Dec 2020 23:01:28

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-02T23:02:31', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '4c493b1f-9951-4993-b958-bc13c8d8453d'	System	03 Jan 2021 04:02:44
User entered 'No (N)'	System	03 Jan 2021 04:02:44

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-02T23:02:37', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '4c493b1f-9951-4993-b958-bc13c8d8453d'	System	03 Jan 2021 04:02:44
User entered 'No (N)'	System	03 Jan 2021 04:02:44

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-02T23:02:42', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '4c493b1f-9951-4993-b958-bc13c8d8453d'	System	03 Jan 2021 04:02:44
User entered '02 Jan 2021 23:02:42'	System	03 Jan 2021 04:02:44

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-10T18:11:33', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '14ee7c78-106f-4eca-9a9a-6dba58c38ac4'	System	10 Jan 2021 23:12:33
User entered 'Yes (Y)'	System	10 Jan 2021 23:12:33

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-10T18:11:41', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '14ee7c78-106f-4eca-9a9a-6dba58c38ac4'	System	10 Jan 2021 23:12:33
User entered 'No (N)'	System	10 Jan 2021 23:12:33

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-10T18:11:51', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '14ee7c78-106f-4eca-9a9a-6dba58c38ac4'	System	10 Jan 2021 23:12:33
User entered 'No (N)'	System	10 Jan 2021 23:12:33

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-10T18:12:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '14ee7c78-106f-4eca-9a9a-6dba58c38ac4'	System	10 Jan 2021 23:12:33
User entered 'Yes (Y)'	System	10 Jan 2021 23:12:33

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-10T18:12:15', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '14ee7c78-106f-4eca-9a9a-6dba58c38ac4'	System	10 Jan 2021 23:12:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 23:12:33

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-10T18:12:23', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '14ee7c78-106f-4eca-9a9a-6dba58c38ac4'	System	10 Jan 2021 23:12:33
User entered '10 Jan 2021 18:12:23'	System	10 Jan 2021 23:12:33

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-20T11:45:10', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '753c809f-6061-4fab-abc1-1cfbca45816d'	System	20 Jan 2021 16:45:27
User entered 'No (N)'	System	20 Jan 2021 16:45:27

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-20T11:45:15', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '753c809f-6061-4fab-abc1-1cfbca45816d'	System	20 Jan 2021 16:45:27
User entered 'No (N)'	System	20 Jan 2021 16:45:27

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-01-20T11:45:22', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '753c809f-6061-4fab-abc1-1cfbca45816d'	System	20 Jan 2021 16:45:27
User entered '20 Jan 2021 11:45:22'	System	20 Jan 2021 16:45:27

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-01T11:24:05', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'c7174855-f842-460f-8ff8-3f4f12cfd385'	System	01 Feb 2021 16:24:27
User entered 'No (N)'	System	01 Feb 2021 16:24:27

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-01T11:24:14', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'c7174855-f842-460f-8ff8-3f4f12cfd385'	System	01 Feb 2021 16:24:27
User entered 'No (N)'	System	01 Feb 2021 16:24:27

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-01T11:24:25', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'c7174855-f842-460f-8ff8-3f4f12cfd385'	System	01 Feb 2021 16:24:27
User entered '01 Feb 2021 11:24:25'	System	01 Feb 2021 16:24:27

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-06T14:34:25', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a056a6bf-2073-4808-ac2b-b18a6fdf0996'	System	06 Feb 2021 19:34:39
User entered 'No (N)'	System	06 Feb 2021 19:34:39

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-06T14:34:30', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a056a6bf-2073-4808-ac2b-b18a6fdf0996'	System	06 Feb 2021 19:34:39
User entered 'No (N)'	System	06 Feb 2021 19:34:39

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-06T14:34:35', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'a056a6bf-2073-4808-ac2b-b18a6fdf0996'	System	06 Feb 2021 19:34:39
User entered '06 Feb 2021 14:34:35'	System	06 Feb 2021 19:34:39

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-15T10:19:32', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'e889cb0b-1e11-4b72-9e13-f96f73ee98a5'	System	15 Feb 2021 15:19:44
User entered 'No (N)'	System	15 Feb 2021 15:19:44

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-15T10:19:36', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'e889cb0b-1e11-4b72-9e13-f96f73ee98a5'	System	15 Feb 2021 15:19:44
User entered 'No (N)'	System	15 Feb 2021 15:19:44

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-15T10:19:41', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'e889cb0b-1e11-4b72-9e13-f96f73ee98a5'	System	15 Feb 2021 15:19:44
User entered '15 Feb 2021 10:19:41'	System	15 Feb 2021 15:19:44

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-20T02:01:23', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6544f507-6a9b-463d-8be8-35a2759148a5'	System	20 Feb 2021 07:01:39
User entered 'No (N)'	System	20 Feb 2021 07:01:39

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-20T02:01:30', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6544f507-6a9b-463d-8be8-35a2759148a5'	System	20 Feb 2021 07:01:39
User entered 'No (N)'	System	20 Feb 2021 07:01:39

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-02-20T02:01:37', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '6544f507-6a9b-463d-8be8-35a2759148a5'	System	20 Feb 2021 07:01:39
User entered '20 Feb 2021 02:01:37'	System	20 Feb 2021 07:01:39

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-01T12:01:24-05:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '94af7b88-1d8b-48ae-8d29-207351b811da'	System	01 Mar 2021 17:07:22
User entered 'No (N)'	System	01 Mar 2021 17:07:22

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-01T12:01:28-05:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '94af7b88-1d8b-48ae-8d29-207351b811da'	System	01 Mar 2021 17:07:22
User entered 'No (N)'	System	01 Mar 2021 17:07:22

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-01T12:01:34-05:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '94af7b88-1d8b-48ae-8d29-207351b811da'	System	01 Mar 2021 17:07:22
User entered '01 Mar 2021 12:01:34'	System	01 Mar 2021 17:07:22

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-08T11:16:22-05:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'b3ab0d9a-e6f8-4c2b-8eec-f36e9027f065'	System	08 Mar 2021 16:16:44
User entered 'No (N)'	System	08 Mar 2021 16:16:44

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-08T11:16:33-05:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'b3ab0d9a-e6f8-4c2b-8eec-f36e9027f065'	System	08 Mar 2021 16:16:44
User entered 'No (N)'	System	08 Mar 2021 16:16:44

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-08T11:16:38-05:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'b3ab0d9a-e6f8-4c2b-8eec-f36e9027f065'	System	08 Mar 2021 16:16:44
User entered '08 Mar 2021 11:16:38'	System	08 Mar 2021 16:16:44

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-14T01:38:51-05:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '1a52936d-c6e7-4294-877f-0b9b170fa889'	System	14 Mar 2021 06:39:09
User entered 'No (N)'	System	14 Mar 2021 06:39:09

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-14T01:38:59-05:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '1a52936d-c6e7-4294-877f-0b9b170fa889'	System	14 Mar 2021 06:39:09
User entered 'No (N)'	System	14 Mar 2021 06:39:09

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-14T01:39:06-05:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '1a52936d-c6e7-4294-877f-0b9b170fa889'	System	14 Mar 2021 06:39:09
User entered '14 Mar 2021 01:39:06'	System	14 Mar 2021 06:39:09

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-22T10:47:55-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '5978a197-10ac-4851-8d65-3406c7afacdb'	System	22 Mar 2021 14:48:06
User entered 'No (N)'	System	22 Mar 2021 14:48:06

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-22T10:47:58-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '5978a197-10ac-4851-8d65-3406c7afacdb'	System	22 Mar 2021 14:48:06
User entered 'No (N)'	System	22 Mar 2021 14:48:06

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-22T10:48:01-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '5978a197-10ac-4851-8d65-3406c7afacdb'	System	22 Mar 2021 14:48:06
User entered '22 Mar 2021 10:48:01'	System	22 Mar 2021 14:48:06

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-31T13:39:16-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'b61e26e0-a80a-48fc-beff-73adea843189'	System	31 Mar 2021 17:39:28
User entered 'No (N)'	System	31 Mar 2021 17:39:28

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-31T13:39:20-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'b61e26e0-a80a-48fc-beff-73adea843189'	System	31 Mar 2021 17:39:28
User entered 'No (N)'	System	31 Mar 2021 17:39:28

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-31T13:39:25-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'b61e26e0-a80a-48fc-beff-73adea843189'	System	31 Mar 2021 17:39:28
User entered '31 Mar 2021 13:39:25'	System	31 Mar 2021 17:39:28

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-04-05T21:16:34-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8d9b77f2-146d-4109-8b76-b2de0ce82479'	System	06 Apr 2021 01:17:51
User entered 'No (N)'	System	06 Apr 2021 01:17:51

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-04-05T21:16:40-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8d9b77f2-146d-4109-8b76-b2de0ce82479'	System	06 Apr 2021 01:17:51
User entered 'No (N)'	System	06 Apr 2021 01:17:51

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-04-05T21:16:44-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '8d9b77f2-146d-4109-8b76-b2de0ce82479'	System	06 Apr 2021 01:17:51
User entered '05 Apr 2021 21:16:44'	System	06 Apr 2021 01:17:51

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-04-10T00:13:50-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'eb1db724-b745-41a9-aaff-6204269bdc6a'	System	10 Apr 2021 04:14:03
User entered 'No (N)'	System	10 Apr 2021 04:14:03

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-04-10T00:13:55-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'eb1db724-b745-41a9-aaff-6204269bdc6a'	System	10 Apr 2021 04:14:03
User entered 'No (N)'	System	10 Apr 2021 04:14:03

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-04-10T00:13:58-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: 'eb1db724-b745-41a9-aaff-6204269bdc6a'	System	10 Apr 2021 04:14:03
User entered '10 Apr 2021 00:13:58'	System	10 Apr 2021 04:14:03

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-04-17T00:23:54-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7b84e587-5984-4006-8213-3d5437759478'	System	17 Apr 2021 04:24:43
User entered 'No (N)'	System	17 Apr 2021 04:24:43

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-04-17T00:24:03-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7b84e587-5984-4006-8213-3d5437759478'	System	17 Apr 2021 04:24:43
User entered 'No (N)'	System	17 Apr 2021 04:24:43

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-04-17T00:24:14-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '7b84e587-5984-4006-8213-3d5437759478'	System	17 Apr 2021 04:24:43
User entered '17 Apr 2021 00:24:14'	System	17 Apr 2021 04:24:43

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:39:50

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-05-01T00:49:55-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '50a00c44-15d0-4699-ac78-6ef5e4e69e4a'	System	01 May 2021 05:11:55
User entered 'No (N)'	System	01 May 2021 05:11:55

US3202036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:20

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-05-01T00:50:01-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '50a00c44-15d0-4699-ac78-6ef5e4e69e4a'	System	01 May 2021 05:11:55
User entered 'No (N)'	System	01 May 2021 05:11:55

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-05-01T00:50:07-04:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '50a00c44-15d0-4699-ac78-6ef5e4e69e4a'	System	01 May 2021 05:11:55
User entered '01 May 2021 00:50:07'	System	01 May 2021 05:11:55

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:39:50

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US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:39:50

US3202036
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:39:50
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:39:50

US3202036

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:40:20

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)	25 Apr 2021 03:49:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-01T12:01:50-05:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9b1ef1c2-b6eb-4420-b2c1-40a3d2cdf20e'	System	01 Mar 2021 17:12:23
User entered 'No (N)'	System	01 Mar 2021 17:12:23

US3202036
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 09 Jun 2021 15:40:20
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01BB8F7A-6E0D-4B05-B260-6513F57F9AD7)', Time: '2021-03-01T12:02:12-05:00', User OID: 'PatientReportedOutcome (US3202036)', ODM File OID: '9b1ef1c2-b6eb-4420-b2c1-40a3d2cdf20e'	System	01 Mar 2021 17:12:23
User entered '01 Mar 2021 12:02:12'	System	01 Mar 2021 17:12:23

US3202036
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	26 Mar 2021 12:37:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:24:39
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:15:30

US3202036
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:37:04
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:24:39
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:15:30

US3202036
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:37:04
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:24:39
User entered empty.	zackery harmon (b) (4)	16 Oct 2020 20:15:30

FDA-CBER-2022-1614-0429809

US3202036
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	26 Mar 2021 12:37:04
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:15:30

FDA-CBER-2022-1614-0429810

US3202036
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	26 Mar 2021 12:37:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:24:53
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	16 Oct 2020 20:15:35

FDA-CBER-2022-1614-0429811

US3202036
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:21:34
User entered '1'	System	30 Oct 2020 16:24:53
User entered empty.	System	16 Oct 2020 20:15:35

US3202036
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 17:34:28

FDA-CBER-2022-1614-0429813

US3202036
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User entered '2 Dec 2020'	(b) (4), (b) (6) (b) (4)	02 Dec 2020 17:34:28

FDA-CBER-2022-1614-0429814

US3202036
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:34:28

FDA-CBER-2022-1614-0429815

US3202036
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 17:34:28

FDA-CBER-2022-1614-0429816

US3202036
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	02 Dec 2020 17:36:01

FDA-CBER-2022-1614-0429817

US3202036
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User entered '1'	System	02 Dec 2020 17:36:01

FDA-CBER-2022-1614-0429818

US3202036
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	04 Jan 2021 15:02:21

US3202036
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '4 Jan 2021'	Lilian Nukuna (b) (4) (b) (4)	04 Jan 2021 15:02:21

FDA-CBER-2022-1614-0429820

US3202036
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	04 Jan 2021 15:02:21

US3202036
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	04 Jan 2021 15:02:21

FDA-CBER-2022-1614-0429822

US3202036
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	04 Jan 2021 15:02:27

FDA-CBER-2022-1614-0429823

US3202036
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User entered '1'	System	04 Jan 2021 15:02:27

US3202036
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	02 Feb 2021 22:13:05

FDA-CBER-2022-1614-0429825

US3202036
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '1 Feb 2021'	Lilian Nukuna (b) (4) (b) (4)	02 Feb 2021 22:13:05

FDA-CBER-2022-1614-0429826

US3202036
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	02 Feb 2021 22:13:05

US3202036
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	02 Feb 2021 22:13:05

FDA-CBER-2022-1614-0429828

US3202036
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	02 Feb 2021 22:13:11

FDA-CBER-2022-1614-0429829

US3202036
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:14:08
User entered '1'	System	02 Feb 2021 22:13:11

FDA-CBER-2022-1614-0429830

US3202036
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 13:47:18

FDA-CBER-2022-1614-0429831

US3202036
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '3 Mar 2021'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 13:47:18

FDA-CBER-2022-1614-0429832

US3202036
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Clinic (Clinic)'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 13:47:18

FDA-CBER-2022-1614-0429833

US3202036
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User entered 'VISIT4'	System	03 Mar 2021 13:47:18

FDA-CBER-2022-1614-0429834

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:46:54

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429836

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429837

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User entered empty.	System	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429838

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429839

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429840

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429841

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:46:54

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User entered empty.	System	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429843

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429844

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User entered empty.	System	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429845

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429846

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User entered empty.	System	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429847

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429848

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User entered empty.	System	30 Mar 2021 18:46:54

FDA-CBER-2022-1614-0429849

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14

FDA-CBER-2022-1614-0429850

US3202036
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:20
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14

FDA-CBER-2022-1614-0429851

US3202036
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:20
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 13:51:17

US3202036
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:20
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 13:51:17

US3202036
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 13:51:34

FDA-CBER-2022-1614-0429854

US3202036
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '3 Mar 2021'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 13:51:34

FDA-CBER-2022-1614-0429855

US3202036
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '08:42'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 13:51:34

US3202036
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User entered '3 Mar 2021 08:42'	System	03 Mar 2021 13:51:34

FDA-CBER-2022-1614-0429857

US3202036
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 13:51:40

FDA-CBER-2022-1614-0429858

US3202036
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:59:14
User entered '1'	System	03 Mar 2021 13:51:40

FDA-CBER-2022-1614-0429859

US3202036
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	01 Apr 2021 15:11:05

US3202036
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:11:05

FDA-CBER-2022-1614-0429861

US3202036
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:11:05

US3202036
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 15:11:05

FDA-CBER-2022-1614-0429863

US3202036
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	01 Apr 2021 15:11:08

US3202036
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:24
User entered '1'	System	01 Apr 2021 15:11:08

FDA-CBER-2022-1614-0429865

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 17:57:53

FDA-CBER-2022-1614-0429866

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 17:57:53

FDA-CBER-2022-1614-0429867

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	01 Feb 2021 17:57:53

FDA-CBER-2022-1614-0429868

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 17:57:53

FDA-CBER-2022-1614-0429869

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:20
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 17:58:24

FDA-CBER-2022-1614-0429870

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:20
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:52:37
User entered '0'	Teresa Deese (b) (4)	22 Apr 2021 14:50:53
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:21:37

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:20
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 17:58:24

FDA-CBER-2022-1614-0429872

US3202036

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:40:20

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
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)	22 Apr 2021 18:31:29
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:52:37
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 'done' (Site from DM).	Teresa Deese (b) (4)	22 Apr 2021 14:51:16
User entered 'Amendment 6 or later (Amendment 6 or later)'	Teresa Deese (b) (4)	22 Apr 2021 14:50:53
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)	22 Apr 2021 07:14:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:21:37

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:20
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 17:58:24

FDA-CBER-2022-1614-0429874

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:20
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mRNA-1273 (mRNA-1273)'	Teresa Deese (b) (4)	01 Feb 2021 17:58:24

FDA-CBER-2022-1614-0429875

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:20
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mRNA-1273 (mRNA-1273)'	Teresa Deese (b) (4)	01 Feb 2021 17:58:24

FDA-CBER-2022-1614-0429876

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:20
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mRNA-1273 (mRNA-1273)'	Teresa Deese (b) (4)	01 Feb 2021 17:58:24

FDA-CBER-2022-1614-0429877

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:20
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	Teresa Deese (b) (4)	01 Feb 2021 17:58:24

FDA-CBER-2022-1614-0429878

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:20
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User entered empty.	System	01 Feb 2021 17:58:24

FDA-CBER-2022-1614-0429879

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:20
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User entered empty.	System	01 Feb 2021 17:58:24

FDA-CBER-2022-1614-0429880

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 17:58:44

FDA-CBER-2022-1614-0429881

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 17:58:44

FDA-CBER-2022-1614-0429882

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '12:46'	Teresa Deese (b) (4)	01 Feb 2021 17:58:44

FDA-CBER-2022-1614-0429883

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User entered '1 Feb 2021 12:46'	System	01 Feb 2021 17:58:44

FDA-CBER-2022-1614-0429884

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:40:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 17:58:56

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:40:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 17:58:56

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:40:20
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '12:43'	Teresa Deese (b) (4)	01 Feb 2021 17:58:56

FDA-CBER-2022-1614-0429887

US3202036
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:40:20
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:06
User entered '1 Feb 2021 12:43'	System	01 Feb 2021 17:58:56

FDA-CBER-2022-1614-0429888

US3202036
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:40:20
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:01:35
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	13 Jan 2021 13:07:23
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:49:38

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
AEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:03:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:03
User entered 'USA-US128-2021-mRNA-1273-P301000007'	System	13 Jan 2021 21:43:59
User entered 'New'	(b) (4), (b) (6)	13 Jan 2021 21:43:59

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:03:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Incarcerated incisional hernia, LLT: Incarcerated incisional hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:10:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:10:55
Data point term sent to Coder	System	14 Jan 2021 22:37:37
Coding entries removed.	Erica Osmundsen (b) (4)	14 Jan 2021 22:36:41
User entered 'WORSENING OF INCARCERATED RECURRENT INCISIONAL VENTRAL HERNIA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	14 Jan 2021 22:36:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia obstructive, LLT: Ventral hernia with obstruction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 14:12:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 14:12:49
Data point term sent to Coder	System	13 Jan 2021 13:11:10
User entered 'INCARCERATED VENTRAL HERNIA (WITH SMALL BOWEL OBSTRUCTION)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429891

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:03:41
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429892

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:03:43
User entered 'No (N)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:03:46
User entered 'No (N)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 15:40:00
DataPoint Un-verified.	(b) (4), (b) (6)	29 Jan 2021 15:39:53
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:04:27
User closed query 'hospital notes indicate transfer from Erlanger East. Please confirm records requested and confirm date of AE/SAE start. Please verify' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 19:14:30
Query 'hospital notes indicate transfer from Erlanger East. Please confirm records requested and confirm date of AE/SAE start. Please verify' answered with 'CONFIRMED--RECORDS RECEIVED ON 12/JAN/2021 FOR DATES 10/JAN2021 AND 11JAN2021, ADDITIONAL RECORDS REQUESTED 13JAN2021 AND RECEIVED ON 14JAN2021 REFLECTING INFORMATION ON 12JAN21 SURGERY. NO D/C DATE NOTED, ADDITIONAL RECORDS WILL BE REQUESTED FOR D/C SUMMARY' (Site from CRA).	Erica Osmundsen (b) (4)	14 Jan 2021 22:41:50
User entered '09 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	14 Jan 2021 22:33:32
User opened query 'hospital notes indicate transfer from Erlanger East. Please confirm records requested and confirm date of AE/SAE start. Please verify' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 21:09:12
User entered '10 Jan 2021'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429895

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:04:32
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429897

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:04:41
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	14 Jan 2021 22:36:41
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:33
User closed query 'PV Query: It was reported that event resolved on 12 Jan 2021. However, subject was discharged on 17 Jan 2021. Please review and reconcile accordingly or provide clarification.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:20:29
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:11:01
Query 'PV Query: It was reported that event resolved on 12 Jan 2021. However, subject was discharged on 17 Jan 2021. Please review and reconcile accordingly or provide clarification.' answered with 'Subject had surgical procedure to correct AE on 12/JAN/2021, but remained in hospital for recovery post-surgery. dates of hospitalization clarified from what subject reported when medical records received' (Site from Safety).	Erica Osmundsen (b) (4)	27 Jan 2021 16:29:23
User opened query 'PV Query: It was reported that event resolved on 12 Jan 2021. However, subject was discharged on 17 Jan 2021. Please review and reconcile accordingly or provide clarification.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 21:14:29
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Jan 2021 21:24:52
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	20 Jan 2021 21:24:52
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Jan 2021 21:24:22
User entered '12 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	14 Jan 2021 22:36:41
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429899

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:11:07
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429900

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Severity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:11:09
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:55:18
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429903

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:03
User entered '0'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:05
User entered '0'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429905

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:33:16
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Jan 2021 21:45:15
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'SUBJECT NOT YET DISCHARGED' (Site from System).	Erica Osmundsen (b) (4)	13 Jan 2021 13:11:05
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Jan 2021 13:10:36
User entered '1'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429906

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:19
User entered '10 Jan 2021'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429907

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 21:46:43
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 16:19:37
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 15:11:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:21
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'RECORDS EMAILED' (Site from Safety).	Erica Osmundsen (b) (4)	27 Jan 2021 17:43:01
User entered '15 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	27 Jan 2021 16:29:43
User closed query 'Per CDM: Please update 'Hospital Discharge Date' once data becomes known. Thanks' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 17:53:55
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:36:56
Query 'Per CDM: Please update 'Hospital Discharge Date' once data becomes known. Thanks' answered by data change (Site from DM).	System	20 Jan 2021 21:24:22
User entered '17 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Jan 2021 21:24:22

FDA-CBER-2022-1614-0429908

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'Per CDM: Please update 'Hospital Discharge Date' once data becomes known. Thanks' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:46:06
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429909

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:26
User entered 'No (N)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:31
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

FDA-CBER-2022-1614-0429911

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:34
User entered '0'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:36
User entered '0'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:39
User entered '0'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

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US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 15:41:33
Query 'please complete source documentation' canceled (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 15:41:31
User opened query 'please complete source documentation' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 15:34:29
DataPoint Un-verified.	(b) (4), (b) (6)	29 Jan 2021 15:34:09
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:42
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:44
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:47
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

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US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:49
User entered '0'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:51
User entered '1'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

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US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:53
User entered '1'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 15:41:42
Query 'please confirm source documentation' canceled (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 15:41:39
User opened query 'please confirm source documentation' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 15:39:19
DataPoint Un-verified.	(b) (4), (b) (6)	29 Jan 2021 15:39:05
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:33:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Jan 2021 21:24:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Jan 2021 21:24:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	14 Jan 2021 22:36:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:34:00
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:11:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 21:46:48
User closed query 'PV Query: Please clarify if small bowel obstruction was also reported as a separate event' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 16:20:19
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)	28 Jan 2021 16:20:15
User closed query 'PV Query: Did the subject receive a COVID-19 test upon admission to the hospital? If yes, please provide type of test, date of test, and result. If no test was performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 16:20:10
Query 'PV Query: Please clarify if small bowel obstruction was also reported as a separate event' answered with 'REPORTED AS PART OF SAME EVENT (ALL ARE ONE DIAGNOSTIC TERM)' (Site from Safety).	Erica Osmundsen (b) (4)	27 Jan 2021 17:44:14
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 'MEDICAL RECORDS DE-IDENTIFIED AND EMAILED MOMENTS AGO' (Site from Safety).	Erica Osmundsen (b) (4)	27 Jan 2021 17:43:44
Query 'PV Query: Did the subject receive a COVID-19 test upon admission to the hospital? If yes, please provide type of test, date of test, and result. If no test was performed, please state so.' answered with 'NO RECORD OF COVID-19 TESTING SEEN IN RECORDS THUS FAR' (Site from Safety).	Erica Osmundsen (b) (4)	27 Jan 2021 17:43:27

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify if small bowel obstruction was also reported as a separate event' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:37:46
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)	21 Jan 2021 15:36:40
User opened query 'PV Query: Did the subject receive a COVID-19 test upon admission to the hospital? If yes, please provide type of test, date of test, and result. If no test was performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:36:25
User entered 'SUBJECT CONTACTED SITE REPORTING RECURRENCE OF VENTRAL HERNIA HAD OCCURRED AND WAS OBSTRUCTING SMALL BOWEL. SHE WAS SCHEDULED TENTATIVELY FOR SURGICAL CORRECTION ON 12/JAN/2021. HOSPITAL ADMISSION RECORDS RECEIVED BUT WILL REQUEST UPDATED RECORDS ON 13JAN2021 FOR SURGICAL RECORD AND INFORMATION ON DISCHARGE WHEN SUBJECT IS D/C'D UPDATE: MEDICAL RECORDS OF SURGERY RECEIVED INDICATE VENTRAL HERNIA REPAIR SURGERY PERFORMED SUCCESSFULLY ON 12JAN2021 BUT NO D/C DATE OR D/C SUMMARY INCLUDED ON RECORDS RECEIVED TO DATE. THESE RECORDS STATE THAT THIS HAS BEEN A RECURRENT ISSUE FOR 4 YEARS, BUT HAD BEEN STABLE W/O SYMPTOMS FOR LONG WHILE PRIOR TO THIS EPISODE. MEDICAL HISTORY UPDATED TO REFLECT THE CONDITION WAS PRESENT AT SCREENING AND AE TERM UPDATED PER MR.' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	14 Jan 2021 22:36:41

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US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Narrative

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE REPORTING RECURRENCE OF VENTRAL HERNIA HAD OCCURRED AND WAS OBSTRUCTING SMALL BOWEL. SHE WAS SCHEDULED TENTATIVELY FOR SURGICAL CORRECTION ON 12/JAN/2021. HOSPITAL ADMISSION RECORDS RECEIVED BUT WILL REQUEST UPDATED RECORDS ON 13JAN2021 FOR SURGICAL RECORD AND INFORMATION ON DISCHARGE WHEN SUBJECT IS D/C'D'	Erica Osmundsen (b) (4)	13 Jan 2021 13:10:36

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US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:20
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Jan 2021 13:10:36

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34

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US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:32:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:32:05
Data point term sent to Coder	System	03 Mar 2021 14:31:33
User entered 'diarrhea'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429931

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

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US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

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US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '28 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Mar 2021 15:27:47
User entered '2 Feb 2021'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429935

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User entered empty.	System	03 Mar 2021 14:31:10

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

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US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '1 Mar 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Mar 2021 15:27:47
User entered '2 Feb 2021'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429938

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User entered empty.	System	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429940

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429941

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429942

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429943

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429944

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429945

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429946

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429947

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429948

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429949

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429951

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429952

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429954

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '1'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429957

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429958

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429961

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User entered '0'	System	03 Mar 2021 14:31:10

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34
User entered '0'	System	03 Mar 2021 14:31:10

FDA-CBER-2022-1614-0429963

US3202036
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:20
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:34

FDA-CBER-2022-1614-0429964

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38

FDA-CBER-2022-1614-0429965

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:33:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:33:09
Data point term sent to Coder	System	03 Mar 2021 14:32:33
User entered 'vomiting'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429966

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429967

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429968

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429969

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '28 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Mar 2021 15:28:09
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 14:32:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 14:32:18
User entered '2 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Mar 2021 14:32:18
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 14:31:54
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429971

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User entered empty.	System	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429972

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429973

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '1 Mar 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Mar 2021 15:28:09
User entered '2 Feb 2021'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429974

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429975

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User entered empty.	System	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429976

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429978

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429979

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429981

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429982

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429983

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429985

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429987

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429988

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429990

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429991

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429992

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '1'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429993

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429994

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:11:33
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:31:54

FDA-CBER-2022-1614-0429997

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User entered '0'	System	03 Mar 2021 14:31:54

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38
User entered '0'	System	03 Mar 2021 14:31:54

US3202036
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:20
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:38

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 09 Jun 2021 15:40:20
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:38:33
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	16 Sep 2020 14:33:51

FDA-CBER-2022-1614-0430001

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:37:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:37:45
Data point term sent to Coder	System	16 Sep 2020 14:36:49
User entered 'TRULICITY'	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

FDA-CBER-2022-1614-0430003

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'TYPE 2 DIABETES MELLITUS'	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '1.5'	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

FDA-CBER-2022-1614-0430005

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'every week (QS)'	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

FDA-CBER-2022-1614-0430008

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'UN UNK 2015'	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '803 (803)'	System	16 Sep 2020 14:36:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:24:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:24:49
Data point term sent to Coder	System	17 Nov 2020 18:23:42
Coding entries removed.	(b) (4), (b) (6)	17 Nov 2020 18:23:09
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:18:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:18:41
Data point term sent to Coder	System	03 Oct 2020 15:17:38
User entered 'Tizanidine'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

FDA-CBER-2022-1614-0430020

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

FDA-CBER-2022-1614-0430021

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:37:46
Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:23:16
User entered 'Back pain' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 18:23:09
User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 22:48:10
User entered 'Muscle spasms'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '4'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mg (mg)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

FDA-CBER-2022-1614-0430025

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'three times daily (TID)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

FDA-CBER-2022-1614-0430028

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'un UNK 2019'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '3'	System	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 15:17:07

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:18:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:18:41
Data point term sent to Coder	System	03 Oct 2020 15:17:38
User entered 'Pantoprazole'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:39:11
Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:19:12
User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 22:22:18
User entered 'GERD'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '40'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mg (mg)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'once daily (QD)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'un UNK 2018'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	27 Jan 2021 16:31:27
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '10 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	27 Jan 2021 16:31:27
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:17:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User entered '1'	System	03 Oct 2020 15:17:33

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User entered '1'	System	03 Oct 2020 15:17:33

FDA-CBER-2022-1614-0430054

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:25
User entered '804 (804)'	System	03 Oct 2020 15:17:33

FDA-CBER-2022-1614-0430055

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 13:41:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 13:41:30
Data point term sent to Coder	System	11 Nov 2020 13:40:28
Coding entries removed.	(b) (4), (b) (6)	11 Nov 2020 13:40:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:19:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:19:42
Data point term sent to Coder	System	03 Oct 2020 15:18:40
User entered 'Gabapentin'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'PER CDM: Please update the indication to reflect the specific location and type of NEUROPATHY (Sensory or Motor). Please reconcile with the Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:36:27
Query 'PER CDM: Please update the indication to reflect the specific location and type of NEUROPATHY (Sensory or Motor). Please reconcile with the Med History eCRFs as appropriate.' answered with 'VERIFIED PER SUBJECT AND CORRECTED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:40:44
User entered 'SENSORY NEUROPATHY' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 13:40:19
User opened query 'PER CDM: Please update the indication to reflect the specific location and type of NEUROPATHY (Sensory or Motor). Please reconcile with the Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:07:57
User entered 'Neuropathy'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '400'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mg (mg)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'three times daily (TID)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'un UNK 2017'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	27 Jan 2021 16:49:02
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '10 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	27 Jan 2021 16:49:02
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User entered '3'	System	03 Oct 2020 15:18:14

FDA-CBER-2022-1614-0430071

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User entered '1'	System	03 Oct 2020 15:18:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:50:30
User entered '804 (804)'	System	03 Oct 2020 15:18:14

FDA-CBER-2022-1614-0430073

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:20:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:20:42
Data point term sent to Coder	System	03 Oct 2020 15:19:40
User entered 'Rosuvastatin'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'HLD'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '5'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

FDA-CBER-2022-1614-0430077

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mg (mg)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'once daily (QD)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'un May 2020'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 15:18:47

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:20:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:20:42
Data point term sent to Coder	System	03 Oct 2020 15:19:42
User entered 'Calcium'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:39:50
Query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' answered with 'DONE' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:03:57
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	17 Nov 2020 18:03:14
User opened query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 02:00:21
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Vitamin supplement'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '600'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mg (mg)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'twice daily (BID)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'un UNK 2019'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 15:19:33

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:22:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:22:10
Data point term sent to Coder	System	03 Oct 2020 15:21:45
User entered 'Raw B complex'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:40:16
Query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'DONE' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:04:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 18:04:24
User opened query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 22:32:41
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Vitamin supplement'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '1'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'tablet (TABLET)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'twice daily (BID)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'un UNK 2019'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:20:54

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 15:20:54

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: VACCINIUM MACROCARPON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 12:18:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 12:18:57
Data point term sent to Coder	System	03 Oct 2020 15:22:46
User entered 'Cranberry supplement'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:40:40
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' answered with 'DONE' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:05:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 18:04:55
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 02:34:29
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'To prevent UTIS'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '4200'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mg (mg)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'once daily (QD)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'un UNK 2019'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 15:21:48

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COQ10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:23:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:23:43
Data point term sent to Coder	System	03 Oct 2020 15:22:45
User entered 'COQ10'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:40:58
Query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' answered with 'DONE' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:14:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 18:14:10
User opened query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 02:33:51
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Vitamin supplement'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '100'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mg (mg)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'twice daily (BID)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'un UNK 2019'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 15:22:42

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:24:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:24:43
Data point term sent to Coder	System	03 Oct 2020 15:23:46
User entered 'Vitamin D3'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:41:17
Query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:14:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 18:14:53
User opened query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 23:22:45
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Vitamin supplement'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '125'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

FDA-CBER-2022-1614-0430167

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'ug (ug)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'once daily (QD)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

FDA-CBER-2022-1614-0430170

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'un UNK 2019'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 15:23:15

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:24:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:24:44
Data point term sent to Coder	System	03 Oct 2020 15:23:46
User entered 'Vitamin E'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:41:45
Query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'DONE' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:15:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 18:15:26
User opened query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 23:24:43
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Vitamin supplement'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '180'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'mg (mg)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'once daily (QD)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

FDA-CBER-2022-1614-0430190

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

FDA-CBER-2022-1614-0430191

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'un UNK 2019'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

FDA-CBER-2022-1614-0430192

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 15:23:37

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 16:57:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 16:57:52
Data point term sent to Coder	System	03 Oct 2020 15:24:47
User entered 'Fluticasone spray'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Seasonal allergies'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '50'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'ug (ug)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

FDA-CBER-2022-1614-0430205

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'once daily (QD)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

FDA-CBER-2022-1614-0430207

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Nasal (NASAL)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'un UNK 2019'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

FDA-CBER-2022-1614-0430210

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

FDA-CBER-2022-1614-0430211

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 15:24:31

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 14:31:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 14:31:00
Data point term sent to Coder	System	13 Jan 2021 13:12:11
User entered 'HYDROMORPHONE'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

FDA-CBER-2022-1614-0430218

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:44
User entered 'No (N)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:42
User entered 'INCARCERATED VENTRAL HERNIA'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:40
User entered '0.5'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:39
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:58:37
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:35
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:33
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:58:31
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:29
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:27
User entered '10 Jan 2021'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:25
User entered '0'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:23
User entered 'No (N)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:21
User entered '10 Jan 2021'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:58:19
User entered 'No (N)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User entered empty.	System	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User entered empty.	System	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:49
User entered empty.	System	13 Jan 2021 13:12:06

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 22:55:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 22:55:58
Data point term sent to Coder	System	14 Jan 2021 22:39:39
User entered 'GENERAL ANESTHESIA (NOT OTHERWISE SPECIFIED)'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:17
User entered 'No (N)'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:55:18
User entered 'INCARCERATED RECURRENT INCISIONAL VENTRAL HERNIA (SURGICAL REPAIR PROCEDURE)'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:20
User entered '1'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:22
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:55:28
User entered 'UNKNOWN DOSE OR MEDICATION--RECORDS NOTE ONLY GENERAL ANESTHESIA WITH ENDOTRACHEAL TUBE'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:40
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:44
User entered empty.	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:45
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:48
User entered empty.	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:51
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:52
User entered '0'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:56
User entered 'No (N)'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:55:58
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:56:00
User entered 'No (N)'	Erica Osmundsen (b) (4)	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User entered empty.	System	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User entered empty.	System	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:51:54
User entered empty.	System	14 Jan 2021 22:39:03

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:00:36
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)	13 Jan 2021 14:52:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 14:52:01
Data point term sent to Coder	System	13 Jan 2021 13:13:11
User entered 'ONDANSETRON'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:09
User entered 'No (N)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: Please review the indication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:01:09
Query 'Per DM CLR: Please review the indication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'this was among Rx given during acute episode of incarcerated hernia' (Site from DM).	Teresa Deese (b) (4)	16 Feb 2021 17:13:15
User opened query 'Per DM CLR: Please review the indication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:54:56
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:11
User entered 'INCARCERATED VENTRAL HERNIA'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:12
User entered '4'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:14
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:15
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:17
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:09:20
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:22
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:23
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:25
User entered '10 Jan 2021'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

FDA-CBER-2022-1614-0430264

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:27
User entered '0'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:57:58
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:01:24
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	16 Feb 2021 17:15:56
DataPoint Un-verified.	Teresa Deese (b) (4)	16 Feb 2021 17:15:48
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	16 Feb 2021 17:15:48
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:55:07
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:29
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:59:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Un-verified.	Teresa Deese (b) (4)	16 Feb 2021 17:15:48
User entered '10 Jan 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	16 Feb 2021 17:15:48
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:31
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:09:32
User entered 'No (N)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User entered empty.	System	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User entered empty.	System	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:04
User entered empty.	System	13 Jan 2021 13:13:10

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:54:32
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)	27 Jan 2021 16:34:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 16:34:14
Data point term sent to Coder	System	27 Jan 2021 16:33:00
User entered 'ACETAMINOPHEN'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:54:34
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:54:36
User entered 'INCARCERATED VENTRAL HERNIA'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

FDA-CBER-2022-1614-0430274

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:54:38
User entered '1000'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

FDA-CBER-2022-1614-0430275

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:54:39
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:54:41
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:54:43
User entered 'three times daily (TID)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:54:44
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:54:47
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

FDA-CBER-2022-1614-0430280

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:54:49
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

FDA-CBER-2022-1614-0430281

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:54:51
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:54:52
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:54:54
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:54:56
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:54:58
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User entered '3'	System	27 Jan 2021 16:32:45

FDA-CBER-2022-1614-0430287

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User entered '1'	System	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:33
User entered '804 (804)'	System	27 Jan 2021 16:32:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:50:53
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)	27 Jan 2021 16:35:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 16:35:15
Data point term sent to Coder	System	27 Jan 2021 16:34:01
User entered 'ACETAMINOPHEN'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:50:56
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:50:57
User entered 'INCARCERATED VENTRAL HERNIA'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:50:59
User entered '650'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:51:01
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:51:03
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:51:05
User entered 'twice daily (BID)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:51:08
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:51:17
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:51:19
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:51:21
User entered '11 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:51:23
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:51:25
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:51:26
User entered '11 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:51:28
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User entered '2'	System	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User entered '1'	System	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:41
User entered '804 (804)'	System	27 Jan 2021 16:33:28

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE HYDROCHLORIDE;EPINEPHRINE, PRODUCTSYNONYM: MARCAINE WITH EPINEPHRINE [BUPIVACAINE HYDROCHLORIDE;EPINEPHRINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 10:16:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 10:16:41
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:44:11
Data point term sent to Coder	System	27 Jan 2021 16:35:02
User entered 'MARCAINE With EPINEPHRINE (BUPIVACAINE 0.5% / EPINEPHRINE 1)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:44:14
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:44:16
User entered 'INCARCERATED VENTRAL HERNIA'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:44:19
User entered '20'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:44:21
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:44:23
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:44:25
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:44:27
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:34:44
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'how reported by facility' (Site from DM).	zackery harmon (b) (4) (b) (4)	01 Mar 2021 21:00:49
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 04:58:13
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:44:30
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:44:34
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:44:36
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:44:38
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:44:40
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:44:42
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:40:46
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User entered empty.	System	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User entered empty.	System	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:05
User entered empty.	System	27 Jan 2021 16:34:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:38:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 01:12:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 01:12:09
Data point term sent to Coder	System	27 Jan 2021 16:36:06
User entered 'LOVENOX'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

FDA-CBER-2022-1614-0430326

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:38:20
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:38:22
User entered 'PREVENTION OF BLOOD CLOTS POST SURGICALLY'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:38:24
User entered '40'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:38:25
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:38:27
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:39:33
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:39:35
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:39:37
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:39:39
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:39:43
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:39:45
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:39:47
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

(b

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:39:49
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:39:51
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User entered empty.	System	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User entered empty.	System	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:18
User entered empty.	System	27 Jan 2021 16:36:04

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN, PRODUCTSYNONYM: NEURONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 14:23:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 14:23:35
Data point term sent to Coder	System	28 Jan 2021 21:40:44
Coding entries removed.	Erica Osmundsen (b) (4)	28 Jan 2021 21:40:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN, PRODUCTSYNONYM: NEURONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 18:52:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 18:52:23
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:37:19
Data point term sent to Coder	System	27 Jan 2021 16:45:33
User entered 'NEURONTIN'	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:37:17
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:59:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Un-verified.	Erica Osmundsen (b) (4)	28 Jan 2021 21:40:37
User entered 'sensory neuropathy' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	28 Jan 2021 21:40:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:37:15
User entered 'INCARCERATED VENTRAL HERNIA'	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

FDA-CBER-2022-1614-0430346

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:37:13
User entered '800'	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

FDA-CBER-2022-1614-0430347

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:37:05
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:37:03
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:37:01
User entered 'three times daily (TID)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:36:59
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'source=oral, please verify' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 21:45:37
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 21:45:33
Query 'source=oral, please verify' answered with 'corrected per source' (Site from CRA).	Erica Osmundsen (b) (4)	28 Jan 2021 21:40:45
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	28 Jan 2021 21:40:37
User opened query 'source=oral, please verify' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 16:36:53
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

FDA-CBER-2022-1614-0430352

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:35:22
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:35:19
User entered '11 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:35:18
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:35:08
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:35:06
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:35:04
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:44:44

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '3'	System	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Jan 2021 16:44:44

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:32:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 16:51:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 16:51:14
Data point term sent to Coder	System	27 Jan 2021 16:50:47
User entered 'DILAUDID'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:32:06
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:32:03
User entered 'INCARCERATED VENTRAL HERNIA'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:32:02
User entered '0.5'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:32:00
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:31:58
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:31:56
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:31:55
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:31:53
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

FDA-CBER-2022-1614-0430370

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:31:51
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

FDA-CBER-2022-1614-0430371

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:31:49
User entered '10 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

FDA-CBER-2022-1614-0430372

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:31:47
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:31:41
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:31:36
User entered '10 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:31:35
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User entered empty.	System	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User entered empty.	System	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:33
User entered empty.	System	27 Jan 2021 16:50:12

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 16:52:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 16:52:04
Data point term sent to Coder	System	27 Jan 2021 16:51:47
User entered 'DILAUDID'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:45
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:30:43
User entered 'INCARCERATED VENTRAL HERNIA'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:41
User entered '0.25'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:38
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:30:36
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:34
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:32
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:30
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:28
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:26
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:24
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

FDA-CBER-2022-1614-0430391

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:20
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:30:18
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User entered empty.	System	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User entered empty.	System	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:47
User entered empty.	System	27 Jan 2021 16:50:49

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:28:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 16:53:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 16:53:05
Data point term sent to Coder	System	27 Jan 2021 16:52:48
User entered 'DILAUDID'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:29:00
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:29:03
User entered 'INCARCERATED VENTRAL HERNIA'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:29:05
User entered '0.5'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:29:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:29:09
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:29:12
User entered 'other (OTHER)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:29:14
User entered 'EVERY 3 HOURS AS NEEDED'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:29:16
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:29:18
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:29:20
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:29:23
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:29:25
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:29:27
User entered '13 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:29:29
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User entered empty.	System	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User entered empty.	System	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:54:04
User entered empty.	System	27 Jan 2021 16:52:14

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING, PRODUCT: INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE, PRODUCTSYNONYM: INSULIN NOVOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 14:25:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 14:25:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:49
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:05
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:26:37
Data point term sent to Coder	System	27 Jan 2021 16:54:49
User entered 'NOVOLIN'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:47
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:03
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:26:40
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:46
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:26:41
User entered 'TYPE 2 DIABETES MELLITUS'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:44
User entered '0-12 SLIDING SCALE'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:42
User entered 'IU (IU)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:27:41
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:39
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:36
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:27:35
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:27:33
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:32
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:30
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:28
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:27
User entered '13 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:27:25
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User entered empty.	System	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User entered empty.	System	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:09
User entered empty.	System	27 Jan 2021 16:54:05

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:21:38
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: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 16:57:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 16:57:04
Data point term sent to Coder	System	27 Jan 2021 16:56:51
User entered 'LACTATED RINGERS'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:21:40
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:21:42
User entered 'PREVENTION OF DEHYDRATION, KEEP VEIN OPEN FOR IV MEDICATION ADMINISTRATION'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:21:44
User entered '125'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:21:45
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:21:47
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:21:49
User entered 'other (OTHER)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:21:59
User entered 'per hour'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:22:04
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:22:06
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:22:08
User entered '10 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:22:09
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:22:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:22:13
User entered '14 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

FDA-CBER-2022-1614-0430447

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:22:15
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User entered empty.	System	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User entered empty.	System	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:13
User entered empty.	System	27 Jan 2021 16:56:11

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
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)	01 Mar 2021 21:06:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 21:06:54
Data point term sent to Coder	System	01 Mar 2021 21:05:49
Coding entries removed.	zackery harmon (b) (4) (b) (4)	01 Mar 2021 21:04:49
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:10
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)	28 Jan 2021 12:45:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 12:45:17
Data point term sent to Coder	System	27 Jan 2021 16:57:52
User entered 'melatonin'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

FDA-CBER-2022-1614-0430452

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:12
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:54:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'Per DM CLR: Please update CM Indication field to reflect a medical condition/diagnosis as appropriate. Please reconcile with the MH or AE eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:35:35
Query 'Per DM CLR: Please update CM Indication field to reflect a medical condition/diagnosis as appropriate. Please reconcile with the MH or AE eCRF as necessary.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	01 Mar 2021 21:05:22
DataPoint Un-verified.	zackery harmon (b) (4) (b) (4)	01 Mar 2021 21:04:49
User entered 'supplement' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	01 Mar 2021 21:04:49
User opened query 'Per DM CLR: Please update CM Indication field to reflect a medical condition/diagnosis as appropriate. Please reconcile with the MH or AE eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 04:58:54
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:15
User entered 'promote sleep and rest'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

FDA-CBER-2022-1614-0430454

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:16
User entered '3'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:23
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:25
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:27
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:19:29
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:31
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:19:33
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:36
User entered '14 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:19:37
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:39
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:41
User entered '14 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:19:43
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User entered '1'	System	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User entered '1'	System	27 Jan 2021 16:57:16

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:12
User entered '804 (804)'	System	27 Jan 2021 16:57:16

FDA-CBER-2022-1614-0430469

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:17:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 17:00:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 17:00:08
Data point term sent to Coder	System	27 Jan 2021 16:58:53
User entered 'robaxin'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:17:45
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:17:46
User entered 'INCARCERATED VENTRAL HERNIA'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:17:48
User entered '500'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:17:50
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:17:52
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:17:55
User entered 'four times daily (QID)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:17:57
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:17:59
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:18:01
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:18:03
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:18:05
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:18:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:18:09
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

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US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:18:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User entered '4'	System	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User entered '1'	System	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:21
User entered '804 (804)'	System	27 Jan 2021 16:57:53

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:13:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: ROXICODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 17:01:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 17:01:03
Data point term sent to Coder	System	27 Jan 2021 16:59:54
User entered 'roxicodone'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:13:57
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:13:59
User entered 'INCARCERATED VENTRAL HERNIA'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:14:01
User entered '5'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:14:03
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:14:04
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:14:06
User entered 'other (OTHER)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:08
User entered 'every 4 hours'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:14:10
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:48
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:14:50
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:14:54
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:14:56
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:14:58
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:15:01
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User entered empty.	System	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User entered empty.	System	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:29
User entered empty.	System	27 Jan 2021 16:59:32

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 15:19:28
User coded data point as Term Coded data point by User: (b) (4) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 15:19:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:13:19
Data point term sent to Coder	System	27 Jan 2021 17:00:55
User entered 'protonix'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:13:17
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:13:15
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:13:13
User entered '40'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:13:10
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:13:07
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:13:04
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:13:02
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:13:01
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:59
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:57
User entered '11 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:55
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:53
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:49
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:46
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User entered '1'	System	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User entered '1'	System	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:36
User entered '804 (804)'	System	27 Jan 2021 17:00:39

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 15:25:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:02:17
Data point term sent to Coder	System	27 Jan 2021 17:02:56
User entered 'PROTONIX'	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:02:20
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:02:22
User entered 'GASTRESOPHAGEAL REFLUX DISEASE'	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:02:24
User entered '40'	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:02:35
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:07:42
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:07:44
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:07:49
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

FDA-CBER-2022-1614-0430531

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:16
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:19
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:21
User entered '13 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:25
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:29
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

FDA-CBER-2022-1614-0430537

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:32
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Jan 2021 17:02:01

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: ANTISEPTICS, PRODUCT: PHENOL, PRODUCTSYNONYM: CHLORASEPTIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:45:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:45:39
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:53
Data point term sent to Coder	System	27 Jan 2021 17:03:57
User entered 'PHENOL 1.4% AEROSOL SPRAY (CHLORASEPTIC)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

FDA-CBER-2022-1614-0430542

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:55
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:59
User entered 'IMPROVE NASOGASTRIC TUBE INSERTION PROCEDURE'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:01
User entered '1'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:03
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:07
User entered 'SPRAY'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:10
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:12
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:14
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:16
User entered empty.	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:17
User entered '10 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:20
User entered '0'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:21
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:24
User entered '10 Jan 2021'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

FDA-CBER-2022-1614-0430555

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:25
User entered 'No (N)'	Erica Osmundsen (b) (4)	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User entered empty.	System	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User entered empty.	System	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:56:55
User entered empty.	System	27 Jan 2021 17:03:52

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ADSORBENTS, ATC: BISMUTH PREPARATIONS, PRODUCT: BISMUTH SUBSALICYLATE, PRODUCTSYNONYM: PEPTO-BISMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:34:29
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 Mar 2021 10:34:29
Data point term sent to Coder	System	03 Mar 2021 14:34:34
User entered 'pepto bismol caplets (brand)'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

FDA-CBER-2022-1614-0430561

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'diarrhea/vomiting'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '2'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'tablet (TABLET)'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	03 Mar 2021 15:29:01
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	03 Mar 2021 15:29:01
User entered 'as needed (PRN)' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Mar 2021 15:29:01
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	03 Mar 2021 15:28:47
User entered 'once (ONCE)'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

FDA-CBER-2022-1614-0430566

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

FDA-CBER-2022-1614-0430568

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered empty.	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '28 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Mar 2021 15:28:47
User entered '2 Feb 2021'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '0'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered '1 Mar 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Mar 2021 15:28:47
User entered '2 Feb 2021'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User entered 'No (N)'	Teresa Deese (b) (4)	03 Mar 2021 14:33:45

FDA-CBER-2022-1614-0430574

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:40:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:33:45

US3202036
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 15:40:20
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
User closed query 'please enter only treatment procedures' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 14:58:33
Query 'please enter only treatment procedures' answered with 'updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	29 Jan 2021 16:01:51
User opened query 'please enter only treatment procedures' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 15:55:50
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:31

US3202036
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 15:40:20
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:07:44
User entered '10 Jan 2021'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:58

US3202036
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 15:40:20
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:07:46
User entered 'NASOGASTRIC TUBE PLACEMENT'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:58

FDA-CBER-2022-1614-0430580

US3202036
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:07:48
User entered 'Adverse Event (AE)'	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:58

US3202036
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 15:40:20
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:07:51
User entered empty.	Erica Osmundsen (b) (4)	13 Jan 2021 13:13:58

FDA-CBER-2022-1614-0430582

US3202036
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 15:40:20
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:08:03
User entered '12 Jan 2021'	Erica Osmundsen (b) (4)	14 Jan 2021 22:37:11

US3202036
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 15:40:20
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:08:03
User entered 'VENTRAL HERNIA REPAIR SURGERY'	Erica Osmundsen (b) (4)	14 Jan 2021 22:37:11

US3202036
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 15:40:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:08:03
User entered 'Adverse Event (AE)'	Erica Osmundsen (b) (4)	14 Jan 2021 22:37:11

US3202036
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 15:40:20
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:08:03
User entered empty.	Erica Osmundsen (b) (4)	14 Jan 2021 22:37:11

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'USA-US128-2021-MRNA-1273-P301000007'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Yes (Y)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Yes (Y)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Mark'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'McKenzie'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430597

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430598

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'US'	System	13 Jan 2021 21:44:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	28 Jan 2021 16:21:01
User entered '3'	System	21 Jan 2021 17:06:22
User entered '2'	System	15 Jan 2021 14:48:37
User entered '1'	System	13 Jan 2021 21:44:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'USA-US128-2021-MRNA-1273-P301000007'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Yes (Y)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Yes (Y)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Mark'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'McKenzie'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430614

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430615

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'US'	System	13 Jan 2021 21:44:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	28 Jan 2021 16:21:01
User entered '3'	System	21 Jan 2021 17:06:22
User entered '2'	System	15 Jan 2021 14:48:37
User entered '1'	System	13 Jan 2021 21:44:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 15:40:20
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
User entered '13/Jan/2021 16:44'	System	13 Jan 2021 21:44:20

US3202036

Folder: SAE USA-US128-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:40:20

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)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered '1'	(b) (4), (b) (6)	13 Jan 2021 21:44:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'USA-US128-2021-MRNA-1273-P301000007'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Yes (Y)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Yes (Y)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Mark'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'McKenzie'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430631

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430632

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430633

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430634

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'US'	System	13 Jan 2021 21:44:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	28 Jan 2021 16:21:01
User entered '3'	System	21 Jan 2021 17:06:22
User entered '2'	System	15 Jan 2021 14:48:37
User entered '1'	System	13 Jan 2021 21:44:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 15:40:20
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
User entered '15/Jan/2021 14:48'	System	15 Jan 2021 14:48:37

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 15:40:20
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)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
User entered '1'	(b) (4), (b) (6)	15 Jan 2021 14:48:37

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'USA-US128-2021-MRNA-1273-P301000007'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Yes (Y)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Yes (Y)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Mark'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'McKenzie'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430649

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430650

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'US'	System	13 Jan 2021 21:44:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	28 Jan 2021 16:21:01
User entered '3'	System	21 Jan 2021 17:06:22
User entered '2'	System	15 Jan 2021 14:48:37
User entered '1'	System	13 Jan 2021 21:44:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 15:40:20
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
User entered '21/Jan/2021 12:06'	System	21 Jan 2021 17:06:22

US3202036

Folder: SAE USA-US128-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:40:20

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)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 16:21:13
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
User entered '1'	(b) (4), (b) (6)	21 Jan 2021 17:06:22

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'USA-US128-2021-MRNA-1273-P301000007'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Yes (Y)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Yes (Y)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'No (N)'	System	13 Jan 2021 21:43:59

FDA-CBER-2022-1614-0430664

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'Mark'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 21:44:10
User entered 'McKenzie'	System	13 Jan 2021 21:43:59

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered '6035 SHALLOWFORD ROAD'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430667

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430668

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'TN'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:06:10
Un-reviewed for Safety.	System	15 Jan 2021 14:48:37
User entered empty.	System	15 Jan 2021 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered '37421'	Erica Osmundsen (b) (4)	13 Jan 2021 21:52:20

FDA-CBER-2022-1614-0430670

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:17:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:41:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 14:48:30
User entered 'US'	System	13 Jan 2021 21:44:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:20
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	28 Jan 2021 16:21:01
User entered '3'	System	21 Jan 2021 17:06:22
User entered '2'	System	15 Jan 2021 14:48:37
User entered '1'	System	13 Jan 2021 21:44:20

US3202036
Folder: SAE USA-US128-2021-MRNA-1273-P301000007
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 15:40:20
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:45:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
User entered '28/Jan/2021 11:20'	(b) (4) System	28 Jan 2021 16:21:01

US3202036

Folder: SAE USA-US128-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:40:20

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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:45:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:17:47
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 16:21:13
User entered '1'	(b) (4), (b) (6)	28 Jan 2021 16:21:01