US3012263 (Prod: Benchmark Research-Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:48:47

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US3012263
Form: Participant Creation
Data signed: (b) (4) **26 Mar 2021 01:03:04**
Generated On: 09 Jun 2021 14:48:47

Participant ID   US3012263

mRNA-1273-P301 Completion Guidelines

US3012263

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 20:52:44

Generated On: 09 Jun 2021 14:48:47

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	50
Age Units	YEARS
Age (Derived)	50

Sex	
	Female ◯
	Male ⬤

Ethnicity	
	Hispanic or Latino ⬤
	Not Hispanic or Latino ◯
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)

White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Date of Informed Consent *(dd MMM yyyy)*	02 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **12 Feb 2021 20:52:44**

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Did the participant meet all eligibility criteria?　　　　　　　　　　　Yes ●

No ○

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) **12 Feb 2021 20:52:44**

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Were any significant conditions reported?   Yes ⬤

No ◯

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Condition	DIABETES, TYPE II
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Condition	GENERAL MYALGIAS, SECONDARY TO WORK
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Condition	DIABETIC NEUROPATHY, LEFT FOOT SENSORY
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	02 SEP 2020
Time of assessment *(00:00-23:59)*	15:45 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 15:45
Height *(xxx.x)*	66.0 in
Weight *(xxx.x)*	184.2 lb
BMI *(xxx.x)*	29.79282 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed?   Yes ⬤

No ◯

Date of examination *(dd MMM yyyy)*   02 SEP 2020

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

Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **12 Feb 2021 20:52:44**
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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ○ No ●
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ○ No ●
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ○ No ●
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ○ No ●
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ○ No ●
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ○ No ●
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ○ No ●
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ○ No ●
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ○ No ●
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ○ No ●
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ○ No ●
Other	Yes ● No ○
Specify	WORKS 5 DAYS A WEEK WITH 10 OTHER PEOPLE. SHOPPING 3-4 DAYS PER WEEK

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	True
Resides in Nursing Home or Assisted Living Facility	False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **12 Feb 2021 20:52:44**

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

| Was this visit performed? | Yes ● |
| | No ○ |

| Visit date (dd MMM yyyy) | 02 SEP 2020 |

| Was visit performed at the participant's home or at the clinic? | Home ○ |
| | Clinic ● |

| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **12 Feb 2021 20:52:44**

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What was the date of randomization? *(dd MMM yyyy)*	02 SEP 2020
What was the participant's randomization number?	145734

In what Cohort was the participant enrolled?

- >=18 and <65 years and not at risk ⚪
- >=18 and <65 years and at risk ⚫
- >=65 years ⚪

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

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

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)*	02 SEP 2020
Time of assessment *(00:00-23:59)*	15:45 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 15:45
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	90 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

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)*	02 SEP 2020
Time of assessment *(00:00-23:59)*	18:04 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 18:04
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed?   Yes ◯

No ⬤

Date of examination *(dd MMM yyyy)*   _____

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

Was 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)*	02 SEP 2020
What was the treatment time? *(00:00-23:59)*	17:21 (24 HR)
Treatment Date and Time (derived)	02 SEP 2020 17:21
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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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	02 SEP 2020
Collection time *(00:00-23:59)*	16:43 (24 HR)
Collection date and time (derived)	02 SEP 2020 16:43

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Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 20:52:44**
Generated On: 09 Jun 2021 14:48:47

Collection date *(dd MMM yyyy)* — 02 SEP 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:29	02 SEP 2020 16:29
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

                                                                                   No ○

Continuing Flag   1

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	02 SEP 2020 18:00
PC Open Date & Time	02 SEP 2020 17:41
PC Close Date & Time	02 SEP 2020 20:11

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	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	02 SEP 2020 22:28
PC Open Date & Time	02 SEP 2020 21:06
PC Close Date & Time	03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:47

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**	96.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ⬤

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	03 SEP 2020 23:04
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	96.0 °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	05 SEP 2020 08:38
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	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	05 SEP 2020 23:23
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	07 SEP 2020 00:04
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

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**	100.3 °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):

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	07 SEP 2020 21:36
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-0011389

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	08 SEP 2020 21:00
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:48:47

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	02 SEP 2020 18:01
PC Open Date & Time	02 SEP 2020 17:41
PC Close Date & Time	02 SEP 2020 20:11

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

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	02 SEP 2020 22:29
PC Open Date & Time	02 SEP 2020 21:06
PC Close Date & Time	03 SEP 2020 11:59

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:48:47

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	03 SEP 2020 23:05
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

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 08:38
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

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	05 SEP 2020 23:24
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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 00:04
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:48:47

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	07 SEP 2020 21:37
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

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	08 SEP 2020 21:00
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ● |
| | Yes ○ |

PC Time stamp	02 SEP 2020 18:02
PC Open Date & Time	02 SEP 2020 17:41
PC Close Date & Time	02 SEP 2020 20:11

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47

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	○

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ⬤ |
| | Yes ◯ |

PC Time stamp	02 SEP 2020 22:29
PC Open Date & Time	02 SEP 2020 21:06
PC Close Date & Time	03 SEP 2020 11:59

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47

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 ●

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47

	Yes ◯
PC Time stamp	03 SEP 2020 23:05
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:47

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 ●

	Yes ◯
PC Time stamp	05 SEP 2020 08:39
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:47

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-2022-1614-0011407

	Yes ◯
PC Time stamp	05 SEP 2020 23:24
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:47

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-2022-1614-0011409

	Yes ◯
PC Time stamp	07 SEP 2020 00:05
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47

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 ●

	Yes ◯
PC Time stamp	07 SEP 2020 21:39
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

TIMEPOINT	DAY 7

HEADACHE

- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING

- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS

- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ●

FDA-CBER-2022-1614-0011413

	Yes 〇
PC Time stamp	08 SEP 2020 21:01
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3012263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **12 Feb 2021 20:52:43**

Generated On: 09 Jun 2021 14:48:47

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 20:52:43**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3012263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **12 Feb 2021 20:52:43**

Generated On: 09 Jun 2021 14:48:47

| Was Contact Attempted? | Yes ● |
| | No ◯ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 20:52:43**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ⬤

                                                                                                                 No ◯

Continuing Flag   1

Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 20:52:43**
Generated On: 09 Jun 2021 14:48:47

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 20:52:43**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

                                                                                No ○

Continuing Flag   1

US3012263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT2

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	30 SEP 2020
Time of assessment *(00:00-23:59)*	14:04 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 14:04
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	94 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4)　**12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	30 SEP 2020
Time of assessment *(00:00-23:59)*	17:54 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 17:54
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	66 mmHg
Diastolic Blood Pressure units	MMHG

US3012263

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed?   Yes ●

                                                               No ○

Date of examination *(dd MMM yyyy)*   30 SEP 2020

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

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)*	30 SEP 2020
What was the treatment time? *(00:00-23:59)*	17:15 (24 HR)
Treatment Date and Time (derived)	30 SEP 2020 17:15
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-2022-1614-0011425

US3012263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	30 SEP 2020
Collection time *(00:00-23:59)*	16:30 (24 HR)
Collection date and time (derived)	30 SEP 2020 16:30

US3012263

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 20:52:44**
Generated On: 09 Jun 2021 14:48:47

Collection date *(dd MMM yyyy)*			30 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:20	30 SEP 2020 16:20
Nasopharyngeal Swab 2	No		

US3012263

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

                                                                                          No ◯

Continuing Flag   1

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	30 SEP 2020 17:49
PC Open Date & Time	30 SEP 2020 17:35
PC Close Date & Time	30 SEP 2020 20:05

TIMEPOINT	DAY 1, AFTER VACCINATION
	(AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	95.3 °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	30 SEP 2020 22:18
PC Open Date & Time	30 SEP 2020 21:00
PC Close Date & Time	01 OCT 2020 11:59

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:48:47

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**	96.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 OCT 2020 01:11
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:48:47

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	02 OCT 2020 22:49
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.0 °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	04 OCT 2020 00:01
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ◯
	No ◯

Please record your **TEMPERATURE in °F**	

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ◯

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-0011434

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 OCT 2020 00:52
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	95.5 °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	06 OCT 2020 21:52
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

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	30 SEP 2020 17:50
PC Open Date & Time	30 SEP 2020 17:35
PC Close Date & Time	30 SEP 2020 20:05

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

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	30 SEP 2020 22:19
PC Open Date & Time	30 SEP 2020 21:00
PC Close Date & Time	01 OCT 2020 11:59

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	02 OCT 2020 01:12
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

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	02 OCT 2020 22:49
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:47

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	04 OCT 2020 00:02
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

TIMEPOINT	DAY 5

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None ⬭
- Does not interfere with activity ⬭
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ⬭
- Any use of prescription pain reliever or prevents daily activity ⬭

Is there any **REDNESS AT INJECTION SITE**?

- Yes ⬭
- No ⬭

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

_____

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

- Yes ⬭
- No ⬭

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

_____

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

- None ⬭
- Does not interfere with activity ⬭
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ⬭
- Any use of prescription pain reliever or prevents daily activity ⬭

PC Time Stamp	_____
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:48:47

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	06 OCT 2020 00:52
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

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	06 OCT 2020 21:53
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

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 ◯

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ⬤ |
| | Yes ◯ |

PC Time stamp	30 SEP 2020 17:50
PC Open Date & Time	30 SEP 2020 17:35
PC Close Date & Time	30 SEP 2020 20:05

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47

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-2022-1614-0011447

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	30 SEP 2020 22:19
PC Open Date & Time	30 SEP 2020 21:00
PC Close Date & Time	01 OCT 2020 11:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47

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 ●

	Yes ◯
PC Time stamp	02 OCT 2020 01:12
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:47

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 ●

	Yes ◯
PC Time stamp	02 OCT 2020 22:50
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47

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 ⬤

	Yes ◯
PC Time stamp	04 OCT 2020 00:02
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47

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 ◯

Yes ⃝

PC Time stamp	
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47

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 ●

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	Yes ◯
PC Time stamp	06 OCT 2020 00:52
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

TIMEPOINT	DAY 7

HEADACHE

None	●
No interference with activity	○
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	○
Any use of prescription pain reliever or prevents daily activity	○

FATIGUE

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

MUSCLE ACHES ALL OVER BODY

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

JOINT ACHES IN SEVERAL JOINTS

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

NAUSEA/VOMITING

None	●
No interference with activity or 1-2 episodes/24 hours	○
Some interference with activity or >2 episodes/24 hours	○
Prevents daily activity, requires outpatient IV hydration	○

CHILLS

None	●
No interference with activity	○
Some interference with activity not requiring medical attention	○
Prevents daily activity and requires medical attention	○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●

	Yes ◯
PC Time stamp	06 OCT 2020 21:53
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3012263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **12 Feb 2021 20:52:43**

Generated On: 09 Jun 2021 14:48:47

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 7 OCT 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 20:52:43**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit? Yes ⬤

No ◯

Continuing Flag   1

US3012263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **12 Feb 2021 20:52:43**

Generated On: 09 Jun 2021 14:48:47

| Was Contact Attempted? | Yes ● |
| | No ◯ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 20:52:43**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3012263

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **12 Feb 2021 20:52:43**

Generated On: 09 Jun 2021 14:48:47

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 21 OCT 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 20:52:43**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3012263

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT3

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	30 OCT 2020
Time of assessment *(00:00-23:59)*	15:55 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 15:55
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	97 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012263

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

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.

US3012263

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **12 Feb 2021 20:52:44**

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?	Yes	●
	No	○

Collection date *(dd MMM yyyy)*	30 OCT 2020
Collection time *(00:00-23:59)*	16:07 (24 HR)
Collection date and time (derived)	30 OCT 2020 16:07

US3012263
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:52:44**
Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ⬭

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ○
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	17 NOV 2020 13:01:30
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 10:30:24
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 89
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 20:10:15
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 06:17:57
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 05:12:17
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	18 DEC 2020 05:33:12
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	26 DEC 2020 10:47:44
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	01 JAN 2021 00:28:39
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	08 JAN 2021 05:44:37
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 05:52:21
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	22 JAN 2021 06:30:21
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 contact your study clinic immediately. Click below to confirm that you have read this 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	29 JAN 2021 10:16:48
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 10:34:13
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	12 FEB 2021 04:36:35
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 03:16:01
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	26 FEB 2021 03:04:49
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	05 MAR 2021 16:39:30
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	12 MAR 2021 04:48:37
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	19 MAR 2021 12:46:52
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	26 MAR 2021 03:46:03
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	02 APR 2021 03:07:44
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	09 APR 2021 03:44:49
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	16 APR 2021 03:44:57
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	24 APR 2021 15:54:28
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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	30 APR 2021 02:31:08
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 contact your study clinic immediately. Click below to confirm that you have read this 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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	11 MAY 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 contact your study clinic immediately. Click below to confirm that you have read this 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):

Symptom	
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 ◯

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US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	18 MAY 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

Symptom	
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 ⃝

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	25 MAY 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

Symptom	
Fever (Temperature $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	01 JUN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	08 JUN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

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 ◯

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

Symptom	
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 ⭕

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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-2022-1614-0011517

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

Symptom	
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-2022-1614-0011519

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	13 JUL 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	27 JUL 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ○

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	03 AUG 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	10 AUG 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ⬭

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

Symptom	
Fever (Temperature $\geq$ 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 ⬤

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	31 AUG 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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-2022-1614-0011537

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

Symptom	
Fever (Temperature $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

Symptom	
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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

FDA-CBER-2022-1614-0011543

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ⬭

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

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 ⬭

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ⚪

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	02 NOV 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ○

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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-2022-1614-0011557

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	23 NOV 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

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 ◯

FDA-CBER-2022-1614-0011565

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ⚪

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	04 JAN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	11 JAN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	18 JAN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

FDA-CBER-2022-1614-0011575

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	01 FEB 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ⬭

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ⬭

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	01 MAR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 MAR 2022 00:01
Patient Cloud Close Date & Time	08 MAR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ⬭

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	15 MAR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

Symptom	
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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	22 MAR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ⬭

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	29 MAR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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-2022-1614-0011597

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

Symptom	
Fever (Temperature $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	03 MAY 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	10 MAY 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	17 MAY 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	24 MAY 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	31 MAY 2022 23:59

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	07 JUN 2022 23:59

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 $\geq$ 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 ⬭

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ⃝

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	21 JUN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	28 JUN 2022 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	05 JUL 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

Symptom	
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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

FDA-CBER-2022-1614-0011627

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	02 AUG 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	09 AUG 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	16 AUG 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	23 AUG 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ⭘

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	06 SEP 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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-2022-1614-0011641

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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):

Symptom	
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-2022-1614-0011643

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	27 SEP 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT   **DAY 768**

Question	Response
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):

Symptom	
Fever (Temperature $\geq$ 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	

Question	Response
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ⚪

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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-2022-1614-0011651

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 〇 Yes 〇
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 〇 Yes 〇
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately 〇
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 〇 Yes 〇

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 〇
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No 〇 Yes 〇

FDA-CBER-2022-1614-0011653

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	01 NOV 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 $\geq$ 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 ◯

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01
Patient Cloud Close Date & Time	08 NOV 2022 23:59

US3012263

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:48:47

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		02 MAR 2021 06:49:33	

US3012263

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **05 Mar 2021 19:33:17**

Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 NOV 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **05 Mar 2021 19:33:17**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ⬤

                                                                          No ◯

Continuing Flag   1

US3012263

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 01:03:06**

Generated On: 09 Jun 2021 14:48:47

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 29 DEC 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments _____

FDA-CBER-2022-1614-0011662

US3012263

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **26 Mar 2021 01:03:06**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

                                                                                          No ◯

Continuing Flag   1

US3012263

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 01:03:06**

Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **26 Mar 2021 01:03:06**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3012263

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 01:03:06**

Generated On: 09 Jun 2021 14:48:47

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments _____

US3012263

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **26 Mar 2021 01:03:06**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3012263
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **08 Apr 2021 14:58:14**
Generated On: 09 Jun 2021 14:48:47

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	29 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT4

US3012263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **08 Apr 2021 14:58:14**

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	29 MAR 2021
Time of assessment *(00:00-23:59)*	14:16 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 14:16
Temperature *(xxx.x)*	99.1 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	95 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012263

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **08 Apr 2021 14:58:14**

Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed? Yes ●

No ○

Date of examination *(dd MMM yyyy)* 29 MAR 2021

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

US3012263

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **08 Apr 2021 14:58:14**

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	29 MAR 2021
Collection time *(00:00-23:59)*	14:42 (24 HR)
Collection date and time (derived)	29 MAR 2021 14:42

US3012263

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **08 Apr 2021 14:58:14**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

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   _____

US3012263

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ◯

                                                                                             No ◯

Continuing Flag

US3012263
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 14:48:47

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 ◯

Generate Next COVID-19 Assessment	Yes ◯
	No ◯

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	19 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) **09 Apr 2021 20:45:06**

Generated On: 09 Jun 2021 14:48:47

Date of updated informed consent *(dd MMM yyyy)*	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ●
	No ○
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ○
	Amendment 6 or later ●
Date of unblinding *(dd MMM yyyy)*	19 JAN 2021
Participant randomization assignment	mRNA-1273 ○
	Placebo ●
Actual Dose 1	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Actual Dose 2	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Will participant receive mRNA-1273?	Yes ●
	No ○
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Height	66.0 in
Weight	184.6 lb
BMI (xxx.x)	29.85752

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Height	66.0 in
Weight	184.6 lb
BMI *(xxx.x)*	29.85752
Timepoint	Pre-Dose ●
	Post-Dose ◯
Were vital signs assessed?	Yes ●
	No ◯
Date of assessment *(dd MMM yyyy)*	19 JAN 2021
Time of assessment *(00:00-23:59)*	08:33 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 08:33
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ●
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	94 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Height	66.0 in
Weight	184.6 lb
BMI *(xxx.x)*	29.85752
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	19 JAN 2021
Time of assessment *(00:00-23:59)*	10:20 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 10:20
Temperature *(xxx.x)*	98.9 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	96 mmHg
Diastolic Blood Pressure units	MMHG

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed?   Yes ●

                                                           No ○

Date of examination *(dd MMM yyyy)*   19 JAN 2021

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

Was study treatment given?	Yes ⬤
	No ◯

If No, reason not given	
Participant declined due to Adverse Event	◯
Physician withheld dose due to Adverse Event	◯
Death	◯
Lost To Follow-Up	◯
Physician Decision	◯
Pregnancy	◯
Protocol Deviation	◯
Study Terminated by Sponsor	◯
Withdrawal of Consent by Participant	◯
Confirmed COVID-19	◯
Other	◯

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	19 JAN 2021
What was the treatment time? *(00:00-23:59)*	09:46 (24 HR)
Treatment Date and Time (derived)	19 JAN 2021 09:46
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

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?	Yes ⬤
	No ⚪
Collection date *(dd MMM yyyy)*	19 JAN 2021
Collection time *(00:00-23:59)*	08:55 (24 HR)
Collection date and time (derived)	19 JAN 2021 08:55

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	19 JAN 2021
Collection time *(00:00 - 23:59)*	08:51
Collection Date and Time (derived)	19 JAN 2021 08:51

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Yes ⬤

No ◯

Continuing Flag   1

US3012263

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 01:03:06**

Generated On: 09 Jun 2021 14:48:47

| Was Contact Attempted? | Yes ● |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 26 JAN 2021 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

US3012263
Folder: Safety Call OL-D8 (1)
Form: Continuing
Data signed: (b) (4) **26 Mar 2021 01:03:06**
Generated On: 09 Jun 2021 14:48:47

| Is the participant continuing to the next visit? | Yes ● |
| | No ○ |

| Continuing Flag | 1 |
| OLD29 Placebo Flag | 1 |

US3012263
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **26 Mar 2021 01:03:05**
Generated On: 09 Jun 2021 14:48:47

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	01 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	OLD29

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	01 MAR 2021
Time of assessment *(00:00-23:59)*	13:20 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 13:20
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	86 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	89 mmHg
Diastolic Blood Pressure units	MMHG

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	01 MAR 2021
Time of assessment *(00:00-23:59)*	15:31 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 15:31
Temperature *(xxx.x)*	99.4 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	86 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	98 mmHg
Diastolic Blood Pressure units	MMHG

Was the physical examination performed?   Yes ●

     No ○

Date of examination *(dd MMM yyyy)*   01 MAR 2021

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

Was study treatment given?	Yes ●
	No ○

If No, reason not given	
Participant declined due to Adverse Event	○
Physician withheld dose due to Adverse Event	○
Death	○
Lost To Follow-Up	○
Physician Decision	○
Pregnancy	○
Protocol Deviation	○
Study Terminated by Sponsor	○
Withdrawal of Consent by Participant	○
Confirmed COVID-19	○
Other	○

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	01 MAR 2021
What was the treatment time? *(00:00-23:59)*	14:50 (24 HR)
Treatment Date and Time (derived)	01 MAR 2021 14:50
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

US3012263
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **26 Mar 2021 01:03:05**
Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3012263

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 01:03:06**

Generated On: 09 Jun 2021 14:48:47

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 8 MAR 2021 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) **26 Mar 2021 01:03:06**

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3012263
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **08 Apr 2021 14:58:14**
Generated On: 09 Jun 2021 14:48:47

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	29 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	OLD57

US3012263

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) **08 Apr 2021 14:58:14**

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	29 MAR 2021
Time of assessment *(00:00-23:59)*	14:16 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 14:16
Temperature *(xxx.x)*	99.1 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	95 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012263

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) **08 Apr 2021 14:58:14**

Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed?   Yes ●

                                                                                                                                       No ○

Date of examination *(dd MMM yyyy)*   29 MAR 2021

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

Was the sample collected?	Yes ⬤
	No ◯

Collection date *(dd MMM yyyy)*	29 MAR 2021
Collection time *(00:00-23:59)*	14:42 (24 HR)
Collection date and time (derived)	29 MAR 2021 14:42

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) **26 Mar 2021 01:03:06**

Generated On: 09 Jun 2021 14:48:47

Visit Date	19 JAN 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Vital Signs

Data signed: (b) (4) **26 Mar 2021 01:03:06**

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	19 JAN 2021
Time of assessment *(00:00-23:59)*	10:22 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 10:22
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)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012263

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **12 Mar 2021 19:39:48**

Generated On: 09 Jun 2021 14:48:47

Did the participant experience any adverse events?　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

If Yes, enter details on the Adverse Events form.

AEID	
Adverse event	LOOSE MOLAR
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)*	15 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	16 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ●
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:22:25

Generated On: 09 Jun 2021 14:48:47

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ●
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ○

Other action taken (check all that apply)

None	False
Concomitant Medication	False
Concomitant Procedure	True

Outcome

- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ●
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ○
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative	MOLAR EXTRACTION DUE TO LOOSE MOLAR
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **16 Apr 2021 15:22:25**

Generated On: 09 Jun 2021 14:48:47

AEID	USA-US006-2020-MRNA-1273-P30 1000003
Adverse event	GUNSHOT WOUND, RIGHT SHOULDER AND SPINE

Was this a medically-attended AE?   Yes ● No ○

Was this a Solicited Adverse Reaction?   Yes ○ No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?   Yes ○ No ●

Start date *(dd MMM yyyy)*	08 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	01 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	09 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	15 NOV 2020

Admitted to ICU?   Yes ○ No ● Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product
- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure
- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product
- None ◯
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome
- Fatal ◯
- Not Recovered/Not Resolved ◯
- Recovered/Resolved ⬤
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

US3012263
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **16 Apr 2021 15:22:25**
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	SUBJECT REPORTED BEING SHOT DURING AN INVASION/BREAK IN AT HIS HOME. SUBJECT WAS SHOT TWICE, ONCE IN THE RIGHT SHOULDER AND THE SECOND PIERCED BOTH LUNGS CAUSING COLLAPSE AND IS CURRENTLY LODGED IN SUBJECT'S SPINE. CURRENTLY HOSPITALIZED.
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

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 15:22:25

Generated On: 09 Jun 2021 14:48:47

AEID	USA-US006-2020-MRNA-1273-P30 1000003
Adverse event	BILATERAL LUNG COLLAPSE

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 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?　Yes ○　No ●

If not Ongoing, end date *(dd MMM yyyy)*	15 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity　Grade 1/Mild ○　Grade 2/Moderate ○　Grade 3/Severe ○　Grade 4 ●

Is the adverse event serious?　Yes ●　No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	08 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	15 NOV 2020

Admitted to ICU?　Yes ○　No ●　Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	None ○
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	False
Concomitant Procedure	True

Outcome	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ●
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ○
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 15:22:25

Generated On: 09 Jun 2021 14:48:47

	SUBJECT REPORTED BEING SHOT DURING AN INVASION/BREAK IN AT HIS HOME. SUBJECT WAS SHOT TWICE, ONCE IN THE RIGHT SHOULDER AND THE SECOND PIERCED BOTH LUNGS CAUSING COLLAPSE AND IS CURRENTLY LODGED IN SUBJECT'S SPINE. CURRENTLY HOSPITALIZED.
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

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 15:22:25

Generated On: 09 Jun 2021 14:48:47

AEID	
Adverse event	POST-TRAUMATIC ANXIETY
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 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, end date *(dd MMM yyyy)*	
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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

AEID	
Adverse event	RASH, BACK AND BUTTOCKS NON UTICARIAL

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)	15 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	

Ongoing?	Yes ○
	No ●

If not Ongoing, end date (dd MMM yyyy)	22 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	

Severity	Grade 1/Mild ●
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ○

Is the adverse event serious?	Yes ○
	No ●

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ●
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ○
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) **16 Apr 2021 15:22:25**

Generated On: 09 Jun 2021 14:48:47

AEID	
Adverse event	COMPOUND FRACTURE, T4 AND T3 RIBS, SECONDARY TO GUNSHOT WOUND

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 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ⬤   No ◯

If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity   Grade 1/Mild ◯   Grade 2/Moderate ◯   Grade 3/Severe ⬤   Grade 4 ◯

Is the adverse event serious?   Yes ◯   No ⬤

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU?   Yes ◯   No ◯   Unknown ◯

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ○
- Not Recovered/Not Resolved ●
- Recovered/Resolved ○
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ○
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

AEID

Adverse event	SUBCUTANEOUS EMPHYSEMA DUE TO GUNSHOT WOUND

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 NOV 2020

Start time *(00:00-23:59)*

AE start date and time (derived)

Ongoing?
Yes ○
No ●

  If not Ongoing, end date *(dd MMM yyyy)*   15 NOV 2020

  End time *(00:00-23:59)*

AE End Date and Time (derived)

Severity
Grade 1/Mild ○
Grade 2/Moderate ○
Grade 3/Severe ●
Grade 4 ○

Is the adverse event serious?
Yes ○
No ●

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False

  Hospital Admission Date *(dd MMM yyyy)*

  Hospital Discharge Date *(dd MMM yyyy)*

  Admitted to ICU?
Yes ○
No ○
Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

- None ◯
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ◯
- Not Recovered/Not Resolved ◯
- Recovered/Resolved ⬤
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Were any prior/concomitant medications and/or vaccinations taken?   Yes ●

                                                                                      No ◯

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

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **16 Apr 2021 22:33:51**

Generated On: 09 Jun 2021 14:48:47

Name of Medication	GLYBURIDE/METFORMIN

Prophylaxis

Yes ◯
No ⬤

Indication	DIABETES, TYPE II
Dose per administration	5/500

Dose unit

mg ⬤
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency

once daily ◯
twice daily ⬤
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ◯
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯
Intraocular ◯

Intramuscular	⭘
Respiratory (Inhalation)	⭘
Intralesional	⭘
Intraperiteoneal	⭘
Nasal	⭘
Vaginal	⭘
Rectal	⭘
Intravenous	⭘
Intravenous Bolus	⭘
Intravenous Drip	⭘
Other	⭘

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	UN UNK 2008
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 ⬤

FDA-CBER-2022-1614-0011722

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **16 Apr 2021 22:33:51**

Generated On: 09 Jun 2021 14:48:47

Name of Medication	LISINOPRIL

Prophylaxis

Yes ⦾

No ⬤

Indication	HYPERTENSION
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 ⦾

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 2008
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 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **16 Apr 2021 22:33:51**

Generated On: 09 Jun 2021 14:48:47

Name of Medication	IBUPROFEN

Prophylaxis	Yes	◯
	No	⬤

Indication	GENERAL MYALGIAS

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 2005
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 22:33:51

Generated On: 09 Jun 2021 14:48:47

Name of Medication	GABAPENTIN

Prophylaxis	Yes ○
	No ●

Indication	DIABETIC NEUROPATHY L FOOT SENSORY

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)*	22 JUN 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 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 22:33:51

Generated On: 09 Jun 2021 14:48:47

Name of Medication	IBUPROFEN

Prophylaxis	Yes ⬤ No ⬤

Yes ○
No ⬤

Indication	DIABETIC NEUROPATHY L FOOT SENSORY

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 FEB 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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **16 Apr 2021 22:33:51**

Generated On: 09 Jun 2021 14:48:47

Name of Medication	TYLENOL

Prophylaxis	Yes ⚪
	No ⚫

Indication	CHILLS

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 ⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

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)*	07 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	07 SEP 2020
Was this medication taken for solicited event?	Yes ⬤
	No ◯
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **16 Apr 2021 22:33:51**

Generated On: 09 Jun 2021 14:48:47

Name of Medication	AMOXICILIN

Prophylaxis

Yes ○

No ●

Indication	MOLAR EXTRACTION
Dose per administration	875

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 ◯
	Intraperitoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 SEP 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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **16 Apr 2021 22:33:51**

Generated On: 09 Jun 2021 14:48:47

Name of Medication	NORCO
Prophylaxis	Yes ⭕
	No ⬤
Indication	MOLAR EXTRACTION
Dose per administration	10/325
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)*	16 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 22:33:51

Generated On: 09 Jun 2021 14:48:47

Name of Medication	ROBAXIN
Prophylaxis	Yes ⚪
	No ⚫
Indication	PAIN, DUE TO GUNSHOT WOUND (AE #2)
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	◯
Intraperitoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	09 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-0011738

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 22:33:51

Generated On: 09 Jun 2021 14:48:47

Name of Medication	TYLENOL

Prophylaxis

Yes ◯

No ⬤

Indication	PAIN, DUE TO GUNSHOT WOUND (AE #2)

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) **16 Apr 2021 22:33:51**

Generated On: 09 Jun 2021 14:48:47

Name of Medication	TRAMADOL
Prophylaxis	Yes ○
	No ⬤
Indication	PAIN, DUE TO GUNSHOT WOUND (AE #2)
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)*	15 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 22:33:51

Generated On: 09 Jun 2021 14:48:47

Name of Medication	ALPRAZOLAM

Prophylaxis
- Yes ○
- No ●

Indication	ANXIETY (AE #4)
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)*	18 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬛
If not Ongoing, End date *(dd MMM yyyy)*	15 DEC 2020
Was this medication taken for solicited event?	Yes ⬭
	No ⬛
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬭

FDA-CBER-2022-1614-0011744

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 22:33:51

Generated On: 09 Jun 2021 14:48:47

Name of Medication	METHOCARBAMOL

Prophylaxis

Yes ◯

No ⬤

Indication

PAIN, DUE TO GUNSHOT WOUND (AE #2)

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)*	18 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 22:33:51

Generated On: 09 Jun 2021 14:48:47

Name of Medication	CLOTRIMAZOLE 1%

Prophylaxis	Yes ◯
	No ⬤

Indication	RASH FROM LAYING IN HOSPITAL BED (AE #5)

Dose per administration	1

Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤

If dose unit is Other, specify	APPLICATION

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 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	22 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 22:33:51

Generated On: 09 Jun 2021 14:48:47

Name of Medication	GLIPIZIDE

Prophylaxis

Yes ◯
No ⬤

Indication	DIABETES, TYPE II (WHILE HOSPITALIZED)
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 ◯

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) **16 Apr 2021 22:33:51**

Generated On: 09 Jun 2021 14:48:47

	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)*	09 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 22:33:51

Generated On: 09 Jun 2021 14:48:47

Name of Medication	INSULIN

Prophylaxis

Yes ◯

No ⬤

Indication	DIABETES, TYPE II (WHILE HOSPITALIZED)
Dose per administration	NA

Dose unit

mg ◯

ug ◯

mL ◯

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ⬤

If dose unit is Other, specify	SLIDING SCALE

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)*	09 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ⭕
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 NOV 2020
Was this medication taken for solicited event?	Yes ⭕
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⭕
	803 ⭕
	804 ⬤

Name of Medication _____

Prophylaxis   Yes ◯
                                                         No ◯

Indication _____

Dose per administration _____

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)*

Start date completely unknown

Ongoing?	Yes ◯
	No ◯

If not Ongoing, End date *(dd MMM yyyy)*

Was this medication taken for solicited event?	Yes ◯
	No ◯

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Were any concomitant procedures performed?   Yes ⬤

                                                             No ◯

If yes, please complete Concomitant Procedures form.

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **26 Mar 2021 01:03:05**

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
16 SEP 2020	MOLAR EXTRACTION	Adverse Event	
09 NOV 2020	BILATERAL CHEST TUBE PLACEMENT	Adverse Event	
09 NOV 2020	CT SCAN - CHEST	Adverse Event	
09 NOV 2020	CT SCAN - ABDOMEN AND PELVIS	Adverse Event	
11 NOV 2020	CHEST XRAY	Adverse Event	
12 NOV 2020	CHEST XRAY	Adverse Event	

US3012263
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:48:47

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 ◯

SAEID	USA-US006-2020-MRNA-1273-P30 1000003
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ● No ○
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) **19 Apr 2021 22:04:01**

Generated On: 09 Jun 2021 14:48:47

SAEID	USA-US006-2020-MRNA-1273-P30 1000003
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ●
	No ○
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/NOV/2020 11:30
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

Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Data signed: (b) (4) **19 Apr 2021 22:04:01**
Generated On: 09 Jun 2021 14:48:47

SAEID	USA-US006-2020-MRNA-1273-P30 1000003
Serious	Yes ⬤ No ◯
Death	Yes ◯ No ⬤
Life threatening	Yes ⬤ No ◯
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ◯
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/NOV/2020 20:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Data signed: (b) (4) **19 Apr 2021 22:04:01**
Generated On: 09 Jun 2021 14:48:47

SAEID	USA-US006-2020-MRNA-1273-P30 1000003
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ● No ○
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/NOV/2020 19:34
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

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) **19 Apr 2021 22:04:01**

Generated On: 09 Jun 2021 14:48:47

SAEID	USA-US006-2020-MRNA-1273-P30 1000003
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ● / No ○
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/DEC/2020 07:58
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

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Data signed: (b) (4) **19 Apr 2021 22:04:01**
Generated On: 09 Jun 2021 14:48:47

SAEID	USA-US006-2020-MRNA-1273-P30 1000003
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ●
	No ○
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/DEC/2020 09:43
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

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) **19 Apr 2021 22:04:01**

Generated On: 09 Jun 2021 14:48:47

SAEID	USA-US006-2020-MRNA-1273-P30 1000003
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ● No ○
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/DEC/2020 15:13
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

Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form (7)
Data signed: (b) (4) **19 Apr 2021 22:04:01**
Generated On: 09 Jun 2021 14:48:47

SAEID	USA-US006-2020-MRNA-1273-P30 1000003
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ● / No ○
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/APR/2021 11:32
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

US3012263 (Prod: Benchmark Research-Austin)

US3012263

Form: Participant Creation

Generated On: 09 Jun 2021 14:48:47

Participant ID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:23:33
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'US3012263'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:39:42

FDA-CBER-2022-1614-0011767

US3012263
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:00

US3012263

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:48:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:39:43

FDA-CBER-2022-1614-0011769

US3012263
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:00

US3012263
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'SCRN'	System	02 Sep 2020 22:08:00

US3012263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered (b) (6) 1969'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:39:44

US3012263
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:48:47

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '50'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:48:47

Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'YEARS'	System	02 Sep 2020 22:08:11

US3012263
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:48:47

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered '50'	System	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:47

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Male (M)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:48:47
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:48:47
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:47

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:47

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:47

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:47

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:48:47
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:48:47
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:48:47
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:47

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:47

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:47

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'Sep 2020'	System	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:47

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered '2020'	System	02 Sep 2020 22:08:20

US3012263
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:48:47
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
	(b) (4)	
User entered 'Amendment 3 (3)'	Jennifer Leyva (b) (4)	02 Sep 2020 22:08:20
	(b) (4)	

US3012263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:47

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:47

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:47

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:47

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:39:43

US3012263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:47

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered '1'	System	02 Sep 2020 22:08:23

US3012263
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 14:48:47
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:23

US3012263

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:48:47

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:43

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental and periodontal infections and inflammations, PT: Dental caries, LLT: Dental caries - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:08:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:08:56
Data point term sent to Coder	System	02 Sep 2020 22:10:15
User entered 'dental caries, left molar'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'UN UNK 2018'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:35

FDA-CBER-2022-1614-0011800

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:47

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:47

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
	(b) (4)	
User entered '0'	Jennifer Leyva (b) (4)	02 Sep 2020 22:09:35
	(b) (4)	

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:47

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'Jan 2018'	System	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:47

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered '2018'	System	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:47

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered empty.	System	02 Sep 2020 22:09:35

US3012263
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:48:47
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered empty.	System	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:48:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
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 II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:10:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:10:58
Data point term sent to Coder	System	02 Sep 2020 22:10:15
User entered 'diabetes, type ii'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:48:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'UN UNK 2008'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:48:47

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:48:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:48:47

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:48:47

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'Jan 2008'	System	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:48:47

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered '2008'	System	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:48:47

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered empty.	System	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:48:47

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered empty.	System	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:48:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:10:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:10:57
Data point term sent to Coder	System	02 Sep 2020 22:10:16
User entered 'hypertension'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:48:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'UN UNK 2008'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:48:47

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:48:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:48:47

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:48:47

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'Jan 2008'	System	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:48:47

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered '2008'	System	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:48:47

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered empty.	System	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:48:47

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered empty.	System	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:48:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:21:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:21:58
Data point term sent to Coder	System	02 Sep 2020 22:11:20
User entered 'general myalgias, secondary to work'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'UN UNK 2005'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:48:47

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:48:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:48:47

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:48:47

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'Jan 2005'	System	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:48:47

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered '2005'	System	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:48:47

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered empty.	System	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:48:47

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered empty.	System	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:48:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:51:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:51:33
Data point term sent to Coder	System	29 Oct 2020 20:25:03
Coding entries removed.	Pamela Fidler (b) (4)	29 Oct 2020 20:24:39
User entered 'DIABETIC NEUROPATHY, LEFT FOOT Sensory' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Oct 2020 20:24:39
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 05:54:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 05:54:39
Data point term sent to Coder	System	02 Sep 2020 22:22:37
User entered 'diabetic neuropathy, left foot'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:48:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'UN Feb 2019'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:48:47

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:48:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:48:47

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:48:47

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'Feb 2019'	System	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:48:47

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered '2019'	System	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:48:47

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered empty.	System	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:48:47

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered empty.	System	02 Sep 2020 22:22:11

US3012263
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered '02 Sep 2020'	Jennifer Leyva (b) (4)	02 Sep 2020 22:25:30

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '15:45'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered '02 Sep 2020 15:45'	System	02 Sep 2020 22:25:30

US3012263
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered '66.0' in (b) (4)	Jennifer Leyva (b) (4)	02 Sep 2020 22:25:30
DataPoint set to visible.	System	02 Sep 2020 22:08:23

US3012263
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '184.2' lb	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30
DataPoint set to visible.	System	02 Sep 2020 22:08:23

US3012263
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered '29.79282'	System	02 Sep 2020 22:25:30
DataPoint set to visible.	System	02 Sep 2020 22:08:23

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'kg/m2'	System	02 Sep 2020 22:25:30
DataPoint set to visible.	System	02 Sep 2020 22:08:23

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User closed query 'Per CDM: When "ND" is recorded, the unit should not remain. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:00:38
Query 'Per CDM: When "ND" is recorded, the unit should not remain. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	14 Dec 2020 15:24:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Pamela Fidler (b) (4)	14 Dec 2020 15:24:39
User opened query 'Per CDM: When "ND" is recorded, the unit should not remain. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 12:28:58
User closed query 'Per CDM: per CCG,"ND" should be recorded for TEMPARATURE,PULSE,RESPIRATORY RATE,SYSTOLIC BP, and DIASTOLIC Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:30:10
Query 'Per CDM: per CCG,"ND" should be recorded for TEMPARATURE,PULSE,RESPIRATORY RATE,SYSTOLIC BP, and DIASTOLIC Please update accordingly.' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	13 Oct 2020 15:31:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Pamela Fidler (b) (4)	13 Oct 2020 15:31:03
User opened query 'Per CDM: per CCG,"ND" should be recorded for TEMPARATURE,PULSE,RESPIRATORY RATE,SYSTOLIC BP, and DIASTOLIC Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 12:17:23
User entered '98.5' F	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty; reason for change Data Entry Error	Pamela Fidler (b) (4)	13 Oct 2020 15:31:03
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Pamela Fidler (b) (4)	13 Oct 2020 15:31:03
User entered '90'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'bpm'	System	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Pamela Fidler (b) (4)	13 Oct 2020 15:31:03
User entered '18'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'breaths/min'	System	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Pamela Fidler (b) (4)	13 Oct 2020 15:31:03
User entered '136'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'mmHg'	System	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Pamela Fidler (b) (4)	13 Oct 2020 15:31:03
User entered '84'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User entered 'mmHg'	System	02 Sep 2020 22:25:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09

US3012263
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09

US3012263
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:36

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:36

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Dec 2020 18:54:23
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Works 5 days a week with 10 other people. Shopping 3-4 days per week' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Dec 2020 18:54:23
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

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 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:47

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:45

US3012263

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:48:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:45

US3012263
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47

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 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:45

US3012263
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'VISIT1'	System	02 Sep 2020 22:26:45

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:54:35

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:47

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered '145734'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:54:35

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:47

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:54:35

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:47

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 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:27:19

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:47

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 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:27:19

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:47

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:27:19

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:47

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:27:19

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:47

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:27:19

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:47

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
	(b) (4)	
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:06:04
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'update' (Site from DM).	Pamela Fidler (b) (4)	28 Oct 2020 15:37:36
User entered 'No (N)'	Pamela Fidler (b) (4)	28 Oct 2020 15:37:33
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:35:16
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:01:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:01:47

US3012263
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:48:47
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '15:45'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '02 Sep 2020 15:45'	System	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '98.5' F	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:48:47
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '90'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'bpm'	System	02 Sep 2020 22:30:17

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '18'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

FDA-CBER-2022-1614-0011920

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'breaths/min'	System	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '136'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'mmHg'	System	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '84'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'mmHg'	System	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered '18:04'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '02 Sep 2020 18:04'	System	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '98.4' F	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:48:47

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '80'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'bpm'	System	02 Sep 2020 23:06:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '16'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'breaths/min'	System	02 Sep 2020 23:06:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '136'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'mmHg'	System	02 Sep 2020 23:06:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '87'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'mmHg'	System	02 Sep 2020 23:06:47

Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:25

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:25

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:31

US3012263
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:48:47
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

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 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:31

US3012263
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:48:47

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 22:57:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered '02 Sep 2020'	Jennifer Leyva (b) (4)	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '17:21'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '02 Sep 2020 17:21'	System	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:31

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'ONCE'	System	02 Sep 2020 22:57:31

FDA-CBER-2022-1614-0011954

US3012263
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:48:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:47

FDA-CBER-2022-1614-0011956

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:47

US3012263

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '16:43'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:47

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '02 Sep 2020 16:43'	System	02 Sep 2020 22:30:47

FDA-CBER-2022-1614-0011959

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

FDA-CBER-2022-1614-0011960

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:47

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '16:29'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:47

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '02 Sep 2020 16:29'	System	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:47

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:47

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered empty.	System	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:31:01

US3012263

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '1'	System	02 Sep 2020 22:31:01

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T17:59:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '65b8bdcc-6481-454e-b838-d65936b44265'	System	02 Sep 2020 23:00:16
User entered 'Yes (Y)'	System	02 Sep 2020 23:00:16

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T17:59:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '65b8bdcc-6481-454e-b838-d65936b44265'	System	02 Sep 2020 23:00:16
User entered '98.4'	System	02 Sep 2020 23:00:16

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:00:04', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '65b8bdcc-6481-454e-b838-d65936b44265'	System	02 Sep 2020 23:00:16
User entered 'No (N)'	System	02 Sep 2020 23:00:16

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:00:12', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '65b8bdcc-6481-454e-b838-d65936b44265'	System	02 Sep 2020 23:00:16
User entered '02 Sep 2020 18:00'	System	02 Sep 2020 23:00:16

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '02 Sep 2020 17:41'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '02 Sep 2020 20:11'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:27:15', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ab5bf005-fa33-4e1e-be08-3979477ead79'	System	03 Sep 2020 03:28:27
User entered 'Yes (Y)'	System	03 Sep 2020 03:28:27

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:12', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ab5bf005-fa33-4e1e-be08-3979477ead79'	System	03 Sep 2020 03:28:27
User entered '96.3'	System	03 Sep 2020 03:28:27

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:17', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ab5bf005-fa33-4e1e-be08-3979477ead79'	System	03 Sep 2020 03:28:27
User entered 'No (N)'	System	03 Sep 2020 03:28:27

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ab5bf005-fa33-4e1e-be08-3979477ead79'	System	03 Sep 2020 03:28:27
User entered '02 Sep 2020 22:28'	System	03 Sep 2020 03:28:27

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '02 Sep 2020 21:06'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 2'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:07', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f556ba7a-ac2f-406b-b695-618be924685f'	System	04 Sep 2020 04:04:33
User entered 'Yes (Y)'	System	04 Sep 2020 04:04:33

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:21', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f556ba7a-ac2f-406b-b695-618be924685f'	System	04 Sep 2020 04:04:33
User entered '96.0'	System	04 Sep 2020 04:04:33

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f556ba7a-ac2f-406b-b695-618be924685f'	System	04 Sep 2020 04:04:33
User entered 'No (N)'	System	04 Sep 2020 04:04:33

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:31', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f556ba7a-ac2f-406b-b695-618be924685f'	System	04 Sep 2020 04:04:33
User entered '03 Sep 2020 23:04'	System	04 Sep 2020 04:04:33

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 3'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:06', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '20f868c8-952a-47aa-bf95-f7976ae0073e'	System	05 Sep 2020 13:38:22
User entered 'Yes (Y)'	System	05 Sep 2020 13:38:22

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:11', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '20f868c8-952a-47aa-bf95-f7976ae0073e'	System	05 Sep 2020 13:38:22
User entered '96.0'	System	05 Sep 2020 13:38:22

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:15', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '20f868c8-952a-47aa-bf95-f7976ae0073e'	System	05 Sep 2020 13:38:22
User entered 'No (N)'	System	05 Sep 2020 13:38:22

FDA-CBER-2022-1614-0011995

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '20f868c8-952a-47aa-bf95-f7976ae0073e'	System	05 Sep 2020 13:38:22
User entered '05 Sep 2020 08:38'	System	05 Sep 2020 13:38:22

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 4'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:23:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8dabdf28-d617-4a9b-99fe-ccda12a48a66'	System	06 Sep 2020 04:23:55
User entered 'Yes (Y)'	System	06 Sep 2020 04:23:55

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:23:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8dabdf28-d617-4a9b-99fe-ccda12a48a66'	System	06 Sep 2020 04:23:55
User entered '96.3'	System	06 Sep 2020 04:23:55

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:23:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8dabdf28-d617-4a9b-99fe-ccda12a48a66'	System	06 Sep 2020 04:23:55
User entered 'No (N)'	System	06 Sep 2020 04:23:55

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:23:51', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8dabdf28-d617-4a9b-99fe-ccda12a48a66'	System	06 Sep 2020 04:23:55
User entered '05 Sep 2020 23:23'	System	06 Sep 2020 04:23:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

FDA-CBER-2022-1614-0012004

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 5'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:07', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '52861067-ad13-4285-87cb-8fac601e8ba8'	System	07 Sep 2020 05:04:26
User entered 'Yes (Y)'	System	07 Sep 2020 05:04:26

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '52861067-ad13-4285-87cb-8fac601e8ba8'	System	07 Sep 2020 05:04:26
User entered '96.8'	System	07 Sep 2020 05:04:26

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '52861067-ad13-4285-87cb-8fac601e8ba8'	System	07 Sep 2020 05:04:26
User entered 'No (N)'	System	07 Sep 2020 05:04:26

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '52861067-ad13-4285-87cb-8fac601e8ba8'	System	07 Sep 2020 05:04:26
User entered '07 Sep 2020 00:04'	System	07 Sep 2020 05:04:26

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:48:47
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 6'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:35:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f'	System	08 Sep 2020 02:36:56
User entered 'Yes (Y)'	System	08 Sep 2020 02:36:56

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:36:08', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f'	System	08 Sep 2020 02:36:56
User entered '100.3'	System	08 Sep 2020 02:36:56

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:36:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f'	System	08 Sep 2020 02:36:56
User entered 'Yes (Y)'	System	08 Sep 2020 02:36:56

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:48:47

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 09:50:27
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'MEDICATION HAS BEEN ADDED' (Site from System).	Lamar Box (b) (4) (b) (4)	18 Sep 2020 19:05:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Sep 2020 02:36:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:36:35', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f'	System	08 Sep 2020 02:36:56
User entered '1'	System	08 Sep 2020 02:36:56

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:36:35', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f'	System	08 Sep 2020 02:36:56
User entered '0'	System	08 Sep 2020 02:36:56

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:36:53', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f'	System	08 Sep 2020 02:36:56
User entered '07 Sep 2020 21:36'	System	08 Sep 2020 02:36:56

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 7'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T20:59:51', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9b56be2b-606a-41a0-9707-f7505bb60e5c'	System	09 Sep 2020 02:00:17
User entered 'Yes (Y)'	System	09 Sep 2020 02:00:17

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:06', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9b56be2b-606a-41a0-9707-f7505bb60e5c'	System	09 Sep 2020 02:00:17
User entered '98.1'	System	09 Sep 2020 02:00:17

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9b56be2b-606a-41a0-9707-f7505bb60e5c'	System	09 Sep 2020 02:00:17
User entered 'No (N)'	System	09 Sep 2020 02:00:17

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US3012263
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9b56be2b-606a-41a0-9707-f7505bb60e5c'	System	09 Sep 2020 02:00:17
User entered '08 Sep 2020 21:00'	System	09 Sep 2020 02:00:17

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:28
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:00:35', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8ddb3383-4ff6-4bd3-9892-544d12850254'	System	02 Sep 2020 23:01:11
User entered 'None (1)'	System	02 Sep 2020 23:01:11

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:00:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8ddb3383-4ff6-4bd3-9892-544d12850254'	System	02 Sep 2020 23:01:11
User entered 'No (N)'	System	02 Sep 2020 23:01:11

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:00:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8ddb3383-4ff6-4bd3-9892-544d12850254'	System	02 Sep 2020 23:01:11
User entered 'No (N)'	System	02 Sep 2020 23:01:11

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:00:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8ddb3383-4ff6-4bd3-9892-544d12850254'	System	02 Sep 2020 23:01:11
User entered 'None (1)'	System	02 Sep 2020 23:01:11

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8ddb3383-4ff6-4bd3-9892-544d12850254'	System	02 Sep 2020 23:01:11
User entered '02 Sep 2020 18:01'	System	02 Sep 2020 23:01:11

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '02 Sep 2020 17:41'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '02 Sep 2020 20:11'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dad857da-12e7-4c9d-bc7f-e58fa88635ad'	System	03 Sep 2020 03:29:06
User entered 'None (1)'	System	03 Sep 2020 03:29:06

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dad857da-12e7-4c9d-bc7f-e58fa88635ad'	System	03 Sep 2020 03:29:06
User entered 'No (N)'	System	03 Sep 2020 03:29:06

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:49', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dad857da-12e7-4c9d-bc7f-e58fa88635ad'	System	03 Sep 2020 03:29:06
User entered 'No (N)'	System	03 Sep 2020 03:29:06

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US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:56', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dad857da-12e7-4c9d-bc7f-e58fa88635ad'	System	03 Sep 2020 03:29:06
User entered 'None (1)'	System	03 Sep 2020 03:29:06

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:03', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dad857da-12e7-4c9d-bc7f-e58fa88635ad'	System	03 Sep 2020 03:29:06
User entered '02 Sep 2020 22:29'	System	03 Sep 2020 03:29:06

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '02 Sep 2020 21:06'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 2'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '02af94a6-16c2-4fc4-aae4-27e3b9b696c2'	System	04 Sep 2020 04:05:10
User entered 'None (1)'	System	04 Sep 2020 04:05:10

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '02af94a6-16c2-4fc4-aae4-27e3b9b696c2'	System	04 Sep 2020 04:05:10
User entered 'No (N)'	System	04 Sep 2020 04:05:10

FDA-CBER-2022-1614-0012047

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:48:47
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '02af94a6-16c2-4fc4-aae4-27e3b9b696c2'	System	04 Sep 2020 04:05:10
User entered 'No (N)'	System	04 Sep 2020 04:05:10

FDA-CBER-2022-1614-0012048

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '02af94a6-16c2-4fc4-aae4-27e3b9b696c2'	System	04 Sep 2020 04:05:10
User entered 'None (1)'	System	04 Sep 2020 04:05:10

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '02af94a6-16c2-4fc4-aae4-27e3b9b696c2'	System	04 Sep 2020 04:05:10
User entered '03 Sep 2020 23:05'	System	04 Sep 2020 04:05:10

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 3'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'b832d9dd-7620-49bb-9031-ea7ddbde44ea'	System	05 Sep 2020 13:38:59
User entered 'None (1)'	System	05 Sep 2020 13:38:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:34', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'b832d9dd-7620-49bb-9031-ea7ddbde44ea'	System	05 Sep 2020 13:38:59
User entered 'No (N)'	System	05 Sep 2020 13:38:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:38', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'b832d9dd-7620-49bb-9031-ea7ddbde44ea'	System	05 Sep 2020 13:38:59
User entered 'No (N)'	System	05 Sep 2020 13:38:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:46', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'b832d9dd-7620-49bb-9031-ea7ddbde44ea'	System	05 Sep 2020 13:38:59
User entered 'None (1)'	System	05 Sep 2020 13:38:59

FDA-CBER-2022-1614-0012057

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:53', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'b832d9dd-7620-49bb-9031-ea7ddbde44ea'	System	05 Sep 2020 13:38:59
User entered '05 Sep 2020 08:38'	System	05 Sep 2020 13:38:59

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 4'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:02', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6ada6734-ca6e-41a8-ac2b-43631aa4aa78'	System	06 Sep 2020 04:24:22
User entered 'None (1)'	System	06 Sep 2020 04:24:22

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6ada6734-ca6e-41a8-ac2b-43631aa4aa78'	System	06 Sep 2020 04:24:22
User entered 'No (N)'	System	06 Sep 2020 04:24:22

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:08', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6ada6734-ca6e-41a8-ac2b-43631aa4aa78'	System	06 Sep 2020 04:24:22
User entered 'No (N)'	System	06 Sep 2020 04:24:22

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:15', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6ada6734-ca6e-41a8-ac2b-43631aa4aa78'	System	06 Sep 2020 04:24:22
User entered 'None (1)'	System	06 Sep 2020 04:24:22

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6ada6734-ca6e-41a8-ac2b-43631aa4aa78'	System	06 Sep 2020 04:24:22
User entered '05 Sep 2020 23:24'	System	06 Sep 2020 04:24:22

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

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US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 5'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '97945944-d5f5-461d-8de3-0eef58763301'	System	07 Sep 2020 05:04:51
User entered 'None (1)'	System	07 Sep 2020 05:04:51

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:37', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '97945944-d5f5-461d-8de3-0eef58763301'	System	07 Sep 2020 05:04:51
User entered 'No (N)'	System	07 Sep 2020 05:04:51

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:48:47
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '97945944-d5f5-461d-8de3-0eef58763301'	System	07 Sep 2020 05:04:51
User entered 'No (N)'	System	07 Sep 2020 05:04:51

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '97945944-d5f5-461d-8de3-0eef58763301'	System	07 Sep 2020 05:04:51
User entered 'None (1)'	System	07 Sep 2020 05:04:51

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '97945944-d5f5-461d-8de3-0eef58763301'	System	07 Sep 2020 05:04:51
User entered '07 Sep 2020 00:04'	System	07 Sep 2020 05:04:51

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:48:47
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 6'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:37:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'de19a42b-af8a-4ca3-8f90-4bbb3f67659c'	System	08 Sep 2020 02:37:45
User entered 'None (1)'	System	08 Sep 2020 02:37:45

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:37:15', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'de19a42b-af8a-4ca3-8f90-4bbb3f67659c'	System	08 Sep 2020 02:37:45
User entered 'No (N)'	System	08 Sep 2020 02:37:45

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:37:27', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'de19a42b-af8a-4ca3-8f90-4bbb3f67659c'	System	08 Sep 2020 02:37:45
User entered 'No (N)'	System	08 Sep 2020 02:37:45

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:37:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'de19a42b-af8a-4ca3-8f90-4bbb3f67659c'	System	08 Sep 2020 02:37:45
User entered 'None (1)'	System	08 Sep 2020 02:37:45

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US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:37:41', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'de19a42b-af8a-4ca3-8f90-4bbb3f67659c'	System	08 Sep 2020 02:37:45
User entered '07 Sep 2020 21:37'	System	08 Sep 2020 02:37:45

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 7'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:24', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2ceb9f45-e484-4610-9779-9c46549aedb8'	System	09 Sep 2020 02:00:55
User entered 'None (1)'	System	09 Sep 2020 02:00:55

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:28', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2ceb9f45-e484-4610-9779-9c46549aedb8'	System	09 Sep 2020 02:00:55
User entered 'No (N)'	System	09 Sep 2020 02:00:55

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:34', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2ceb9f45-e484-4610-9779-9c46549aedb8'	System	09 Sep 2020 02:00:55
User entered 'No (N)'	System	09 Sep 2020 02:00:55

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US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2ceb9f45-e484-4610-9779-9c46549aedb8'	System	09 Sep 2020 02:00:55
User entered 'None (1)'	System	09 Sep 2020 02:00:55

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:53', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2ceb9f45-e484-4610-9779-9c46549aedb8'	System	09 Sep 2020 02:00:55
User entered '08 Sep 2020 21:00'	System	09 Sep 2020 02:00:55

US3012263
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:48:47
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:31
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

FDA-CBER-2022-1614-0012094

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:02:02', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:02:11', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'No (N)'	System	02 Sep 2020 23:02:23

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:02:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered '02 Sep 2020 18:02'	System	02 Sep 2020 23:02:23

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '02 Sep 2020 17:41'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '02 Sep 2020 20:11'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:29', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'No (N)'	System	03 Sep 2020 03:29:42

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered '02 Sep 2020 22:29'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '02 Sep 2020 21:06'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 2'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:20', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:28', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:31', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:38', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:41', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:45', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:53', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'No (N)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:56', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered '03 Sep 2020 23:05'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 3'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:58', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:01', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:07', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:11', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:16', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:20', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'No (N)'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered '05 Sep 2020 08:39'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 4'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:24', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

FDA-CBER-2022-1614-0012139

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:29', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:31', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

FDA-CBER-2022-1614-0012141

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:34', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:37', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'No (N)'	System	06 Sep 2020 04:24:51

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered '05 Sep 2020 23:24'	System	06 Sep 2020 04:24:51

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 5'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:05:03', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:05:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:05:09', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'No (N)'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:05:11', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered '07 Sep 2020 00:05'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 6'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:37:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'None (0)'	System	08 Sep 2020 02:39:33

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:38:07', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'None (0)'	System	08 Sep 2020 02:39:33

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:38:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'None (0)'	System	08 Sep 2020 02:39:33

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:38:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'None (0)'	System	08 Sep 2020 02:39:33

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:38:45', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'None (0)'	System	08 Sep 2020 02:39:33

FDA-CBER-2022-1614-0012164

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:39:20', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'Some interference with activity not requiring medical attention (2)'	System	08 Sep 2020 02:39:33

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:39:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'No (N)'	System	08 Sep 2020 02:39:33

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:39:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered '07 Sep 2020 21:39'	System	08 Sep 2020 02:39:33

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 7'	System	02 Sep 2020 22:57:31

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:04', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:25', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:29', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'No (N)'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered '08 Sep 2020 21:01'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:36
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:17:52

US3012263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 05:18:53
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as entered' (Site from System).	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:17:59
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Sep 2020 20:17:52
User entered '16 Sep 2020'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:17:52

US3012263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Contact Made (CONTACT MADE)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:17:52

US3012263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:17:52

US3012263
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:18:05

US3012263
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '1'	System	16 Sep 2020 20:18:05

US3012263
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:24:51

US3012263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
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).	System	25 Sep 2020 22:25:08
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 by data change (Site from System).	System	25 Sep 2020 22:25:08
User entered '18 Sep 2020' reason for change: Data Entry Error	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:08
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	25 Sep 2020 22:24:51
User entered '25 Sep 2020'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:24:51

US3012263
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:24:51

US3012263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:24:51

US3012263

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:13

US3012263

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '1'	System	25 Sep 2020 22:25:13

US3012263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:49

US3012263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '25 Sep 2020'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:49

US3012263
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:49

US3012263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:49

US3012263

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:52

US3012263
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '1'	System	25 Sep 2020 22:25:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:47

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:06:28

US3012263
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:06:28

FDA-CBER-2022-1614-0012200

US3012263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:47

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 16:39:51
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:52:44
User entered 'Clinic (Clinic)'	Katherine Davis (b) (4)	30 Sep 2020 23:06:28

US3012263
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'VISIT2'	System	30 Sep 2020 23:06:28

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User accepted default value 'Pre-Dose (PREDOSE)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '14:04'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '30 Sep 2020 14:04'	System	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '98.2' F	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Oral (Oral)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:48:47
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '94'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:48:47
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'bpm'	System	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '18'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'breaths/min'	System	30 Sep 2020 23:07:14

FDA-CBER-2022-1614-0012214

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '127'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'mmHg'	System	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '74'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'mmHg'	System	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User accepted default value 'Post-Dose (POSTDOSE)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '17:54'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '30 Sep 2020 17:54'	System	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '98.1' F	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Oral (Oral)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:48:47
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '81'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:48:47
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'bpm'	System	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '14'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'breaths/min'	System	30 Sep 2020 23:07:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '104'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'mmHg'	System	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '66'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'mmHg'	System	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:08:02

US3012263

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:47

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:08:02

US3012263
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:48:47

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

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 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

US3012263
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:48:47
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 22:48:10

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:48:47

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:48:47

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '17:15'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '30 Sep 2020 17:15'	System	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Left Arm (LEFT ARM)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'ONCE'	System	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:08:25

Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:48:47

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:08:25

US3012263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '16:30' reason for change: Data Entry Error	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:08:43
User entered '16:20'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:08:25

US3012263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '30 Sep 2020 16:30'	System	30 Sep 2020 23:08:43
User entered '30 Sep 2020 16:20'	System	30 Sep 2020 23:08:25

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:48:47

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:47

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:47

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '16:20'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

US3012263
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:48:47
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '30 Sep 2020 16:20'	System	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:47

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:47

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered empty.	System	30 Sep 2020 23:09:06

US3012263
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:12

US3012263

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '1'	System	30 Sep 2020 23:09:12

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:49:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '01408fd2-037f-4844-ab4f-4cdd18cff8d9'	System	30 Sep 2020 22:49:46
User entered 'Yes (Y)'	System	30 Sep 2020 22:49:46

FDA-CBER-2022-1614-0012263

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:49:24', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '01408fd2-037f-4844-ab4f-4cdd18cff8d9'	System	30 Sep 2020 22:49:46
User entered '98.1'	System	30 Sep 2020 22:49:46

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:49:35', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '01408fd2-037f-4844-ab4f-4cdd18cff8d9'	System	30 Sep 2020 22:49:46
User entered 'No (N)'	System	30 Sep 2020 22:49:46

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:49:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '01408fd2-037f-4844-ab4f-4cdd18cff8d9'	System	30 Sep 2020 22:49:46
User entered '30 Sep 2020 17:49'	System	30 Sep 2020 22:49:46

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '30 Sep 2020 17:35'	System	30 Sep 2020 22:48:10

FDA-CBER-2022-1614-0012267

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '30 Sep 2020 20:05'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:16:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f60b5f87-be6d-4028-8cf7-b644cd7c3a8c'	System	01 Oct 2020 03:18:57
User entered 'Yes (Y)'	System	01 Oct 2020 03:18:57

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:18:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f60b5f87-be6d-4028-8cf7-b644cd7c3a8c'	System	01 Oct 2020 03:18:57
User entered '95.3'	System	01 Oct 2020 03:18:57

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:18:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f60b5f87-be6d-4028-8cf7-b644cd7c3a8c'	System	01 Oct 2020 03:18:57
User entered 'No (N)'	System	01 Oct 2020 03:18:57

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:18:53', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f60b5f87-be6d-4028-8cf7-b644cd7c3a8c'	System	01 Oct 2020 03:18:57
User entered '30 Sep 2020 22:18'	System	01 Oct 2020 03:18:57

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '30 Sep 2020 21:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 2'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:09:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ccee60fd-b636-4103-a4a1-c932697e57ed'	System	02 Oct 2020 06:12:02
User entered 'Yes (Y)'	System	02 Oct 2020 06:12:02

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:11:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ccee60fd-b636-4103-a4a1-c932697e57ed'	System	02 Oct 2020 06:12:02
User entered '96.4'	System	02 Oct 2020 06:12:02

FDA-CBER-2022-1614-0012278

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:47

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:11:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ccee60fd-b636-4103-a4a1-c932697e57ed'	System	02 Oct 2020 06:12:02
User entered 'No (N)'	System	02 Oct 2020 06:12:02

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:11:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ccee60fd-b636-4103-a4a1-c932697e57ed'	System	02 Oct 2020 06:12:02
User entered '02 Oct 2020 01:11'	System	02 Oct 2020 06:12:02

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 3'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:48:27', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4c095c41-e03a-42d4-8ad4-0c0b3b8bcf85'	System	03 Oct 2020 03:49:18
User entered 'Yes (Y)'	System	03 Oct 2020 03:49:18

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:48:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4c095c41-e03a-42d4-8ad4-0c0b3b8bcf85'	System	03 Oct 2020 03:49:18
User entered '96.0'	System	03 Oct 2020 03:49:18

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:48:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4c095c41-e03a-42d4-8ad4-0c0b3b8bcf85'	System	03 Oct 2020 03:49:18
User entered 'No (N)'	System	03 Oct 2020 03:49:18

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:49:17', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4c095c41-e03a-42d4-8ad4-0c0b3b8bcf85'	System	03 Oct 2020 03:49:18
User entered '02 Oct 2020 22:49'	System	03 Oct 2020 03:49:18

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 4'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-03T23:58:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1ec18452-1969-49ce-a33e-c29d082b6554'	System	04 Oct 2020 05:02:14
User entered 'Yes (Y)'	System	04 Oct 2020 05:02:14

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:01:37', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1ec18452-1969-49ce-a33e-c29d082b6554'	System	04 Oct 2020 05:02:14
User entered '96.0'	System	04 Oct 2020 05:02:14

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:01:46', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1ec18452-1969-49ce-a33e-c29d082b6554'	System	04 Oct 2020 05:02:14
User entered 'No (N)'	System	04 Oct 2020 05:02:14

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:01:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1ec18452-1969-49ce-a33e-c29d082b6554'	System	04 Oct 2020 05:02:14
User entered '04 Oct 2020 00:01'	System	04 Oct 2020 05:02:14

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 5'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:48:47
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35

FDA-CBER-2022-1614-0012298

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35

FDA-CBER-2022-1614-0012300

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:48:47

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:48:47
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 6'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:51:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2c8e2c6d-674c-4081-9323-732de40fd4c1'	System	06 Oct 2020 05:52:13
User entered 'Yes (Y)'	System	06 Oct 2020 05:52:13

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:01', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2c8e2c6d-674c-4081-9323-732de40fd4c1'	System	06 Oct 2020 05:52:13
User entered '96.4'	System	06 Oct 2020 05:52:13

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2c8e2c6d-674c-4081-9323-732de40fd4c1'	System	06 Oct 2020 05:52:13
User entered 'No (N)'	System	06 Oct 2020 05:52:13

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2c8e2c6d-674c-4081-9323-732de40fd4c1'	System	06 Oct 2020 05:52:13
User entered '06 Oct 2020 00:52'	System	06 Oct 2020 05:52:13

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 7'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:52:21', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6c9ce927-30de-4fa6-b9aa-fd14629b2734'	System	07 Oct 2020 02:53:01
User entered 'Yes (Y)'	System	07 Oct 2020 02:53:01

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:52:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6c9ce927-30de-4fa6-b9aa-fd14629b2734'	System	07 Oct 2020 02:53:01
User entered '95.5'	System	07 Oct 2020 02:53:01

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:47

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:52:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6c9ce927-30de-4fa6-b9aa-fd14629b2734'	System	07 Oct 2020 02:53:01
User entered 'No (N)'	System	07 Oct 2020 02:53:01

US3012263
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:52:58', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6c9ce927-30de-4fa6-b9aa-fd14629b2734'	System	07 Oct 2020 02:53:01
User entered '06 Oct 2020 21:52'	System	07 Oct 2020 02:53:01

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:35
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:49:49', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c0294395-8971-44ef-af2c-08b27bae9cd4'	System	30 Sep 2020 22:50:22
User entered 'None (1)'	System	30 Sep 2020 22:50:22

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:49:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c0294395-8971-44ef-af2c-08b27bae9cd4'	System	30 Sep 2020 22:50:22
User entered 'No (N)'	System	30 Sep 2020 22:50:22

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:06', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c0294395-8971-44ef-af2c-08b27bae9cd4'	System	30 Sep 2020 22:50:22
User entered 'No (N)'	System	30 Sep 2020 22:50:22

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:11', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c0294395-8971-44ef-af2c-08b27bae9cd4'	System	30 Sep 2020 22:50:22
User entered 'None (1)'	System	30 Sep 2020 22:50:22

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c0294395-8971-44ef-af2c-08b27bae9cd4'	System	30 Sep 2020 22:50:22
User entered '30 Sep 2020 17:50'	System	30 Sep 2020 22:50:22

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '30 Sep 2020 17:35'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '30 Sep 2020 20:05'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:18:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1479d1a8-a00f-4c96-8ae5-aca6b3e36a47'	System	01 Oct 2020 03:19:16
User entered 'None (1)'	System	01 Oct 2020 03:19:16

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:03', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1479d1a8-a00f-4c96-8ae5-aca6b3e36a47'	System	01 Oct 2020 03:19:16
User entered 'No (N)'	System	01 Oct 2020 03:19:16

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US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:07', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1479d1a8-a00f-4c96-8ae5-aca6b3e36a47'	System	01 Oct 2020 03:19:16
User entered 'No (N)'	System	01 Oct 2020 03:19:16

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1479d1a8-a00f-4c96-8ae5-aca6b3e36a47'	System	01 Oct 2020 03:19:16
User entered 'None (1)'	System	01 Oct 2020 03:19:16

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1479d1a8-a00f-4c96-8ae5-aca6b3e36a47'	System	01 Oct 2020 03:19:16
User entered '30 Sep 2020 22:19'	System	01 Oct 2020 03:19:16

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '30 Sep 2020 21:00'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 2'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'acc963c2-f5bc-4278-8a6c-5c5133481f97'	System	02 Oct 2020 06:12:24
User entered 'None (1)'	System	02 Oct 2020 06:12:24

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US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:08', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'acc963c2-f5bc-4278-8a6c-5c5133481f97'	System	02 Oct 2020 06:12:24
User entered 'No (N)'	System	02 Oct 2020 06:12:24

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:12', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'acc963c2-f5bc-4278-8a6c-5c5133481f97'	System	02 Oct 2020 06:12:24
User entered 'No (N)'	System	02 Oct 2020 06:12:24

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'acc963c2-f5bc-4278-8a6c-5c5133481f97'	System	02 Oct 2020 06:12:24
User entered 'None (1)'	System	02 Oct 2020 06:12:24

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:23', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'acc963c2-f5bc-4278-8a6c-5c5133481f97'	System	02 Oct 2020 06:12:24
User entered '02 Oct 2020 01:12'	System	02 Oct 2020 06:12:24

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:48:47
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 3'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:49:23', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9f0a5fd0-78f2-40cd-860e-e981cacdbf10'	System	03 Oct 2020 03:50:01
User entered 'None (1)'	System	03 Oct 2020 03:50:01

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:49:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9f0a5fd0-78f2-40cd-860e-e981cacdbf10'	System	03 Oct 2020 03:50:01
User entered 'No (N)'	System	03 Oct 2020 03:50:01

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:49:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9f0a5fd0-78f2-40cd-860e-e981cacdbf10'	System	03 Oct 2020 03:50:01
User entered 'No (N)'	System	03 Oct 2020 03:50:01

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:49:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9f0a5fd0-78f2-40cd-860e-e981cacdbf10'	System	03 Oct 2020 03:50:01
User entered 'None (1)'	System	03 Oct 2020 03:50:01

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:49:58', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9f0a5fd0-78f2-40cd-860e-e981cacdbf10'	System	03 Oct 2020 03:50:01
User entered '02 Oct 2020 22:49'	System	03 Oct 2020 03:50:01

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 4'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:01:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0553d57c-64ab-498d-ab7e-15813f8673af'	System	04 Oct 2020 05:02:48
User entered 'None (1)'	System	04 Oct 2020 05:02:48

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0553d57c-64ab-498d-ab7e-15813f8673af'	System	04 Oct 2020 05:02:48
User entered 'No (N)'	System	04 Oct 2020 05:02:48

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:04', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0553d57c-64ab-498d-ab7e-15813f8673af'	System	04 Oct 2020 05:02:48
User entered 'No (N)'	System	04 Oct 2020 05:02:48

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:09', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0553d57c-64ab-498d-ab7e-15813f8673af'	System	04 Oct 2020 05:02:48
User entered 'None (1)'	System	04 Oct 2020 05:02:48

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0553d57c-64ab-498d-ab7e-15813f8673af'	System	04 Oct 2020 05:02:48
User entered '04 Oct 2020 00:02'	System	04 Oct 2020 05:02:48

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:48:47
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 5'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41

FDA-CBER-2022-1614-0012362

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:48:47
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:48:47
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 6'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '50cbd953-9cef-426f-9d3f-7420d2e7ac04'	System	06 Oct 2020 05:52:34
User entered 'None (1)'	System	06 Oct 2020 05:52:34

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '50cbd953-9cef-426f-9d3f-7420d2e7ac04'	System	06 Oct 2020 05:52:34
User entered 'No (N)'	System	06 Oct 2020 05:52:34

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '50cbd953-9cef-426f-9d3f-7420d2e7ac04'	System	06 Oct 2020 05:52:34
User entered 'No (N)'	System	06 Oct 2020 05:52:34

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '50cbd953-9cef-426f-9d3f-7420d2e7ac04'	System	06 Oct 2020 05:52:34
User entered 'None (1)'	System	06 Oct 2020 05:52:34

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:47

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:31', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '50cbd953-9cef-426f-9d3f-7420d2e7ac04'	System	06 Oct 2020 05:52:34
User entered '06 Oct 2020 00:52'	System	06 Oct 2020 05:52:34

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:48:47
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 7'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:06', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0138fa85-5e7e-4702-81df-540137bf09e8'	System	07 Oct 2020 02:53:26
User entered 'None (1)'	System	07 Oct 2020 02:53:26

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0138fa85-5e7e-4702-81df-540137bf09e8'	System	07 Oct 2020 02:53:26
User entered 'No (N)'	System	07 Oct 2020 02:53:26

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0138fa85-5e7e-4702-81df-540137bf09e8'	System	07 Oct 2020 02:53:26
User entered 'No (N)'	System	07 Oct 2020 02:53:26

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:48:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0138fa85-5e7e-4702-81df-540137bf09e8'	System	07 Oct 2020 02:53:26
User entered 'None (1)'	System	07 Oct 2020 02:53:26

US3012263
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:48:47
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:21', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0138fa85-5e7e-4702-81df-540137bf09e8'	System	07 Oct 2020 02:53:26
User entered '06 Oct 2020 21:53'	System	07 Oct 2020 02:53:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

FDA-CBER-2022-1614-0012384

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:41
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:34', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:46', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:51', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'No (N)'	System	30 Sep 2020 22:51:01

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:48:47
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered '30 Sep 2020 17:50'	System	30 Sep 2020 22:51:01

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '30 Sep 2020 17:35'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '30 Sep 2020 20:05'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:25', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:41', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'No (N)'	System	01 Oct 2020 03:19:48

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered '30 Sep 2020 22:19'	System	01 Oct 2020 03:19:48

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '30 Sep 2020 21:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 2'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:37', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:41', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'No (N)'	System	02 Oct 2020 06:12:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered '02 Oct 2020 01:12'	System	02 Oct 2020 06:12:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 3'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:29', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'No (N)'	System	03 Oct 2020 03:50:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered '02 Oct 2020 22:50'	System	03 Oct 2020 03:50:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 4'	System	30 Sep 2020 22:48:10

FDA-CBER-2022-1614-0012430

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:27', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:48:47
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'No (N)'	System	04 Oct 2020 05:03:12

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:51', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered '04 Oct 2020 00:02'	System	04 Oct 2020 05:03:12

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 5'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:11:45

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 6'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:45', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'No (N)'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered '06 Oct 2020 00:52'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:48:47
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 7'	System	30 Sep 2020 22:48:10

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:48:47
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:28', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:48:47
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:31', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:48:47
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:34', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:48:47
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:45', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'No (N)'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered '06 Oct 2020 21:53'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:48:47

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:11:45
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	07 Oct 2020 17:30:14

US3012263
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '7 Oct 2020'	Tambra Dora (b) (4) (b) (4)	07 Oct 2020 17:30:14

US3012263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	07 Oct 2020 17:30:14

US3012263
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Tambra Dora (b) (4) (b) (4)	07 Oct 2020 17:30:14

US3012263

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	07 Oct 2020 17:30:17

US3012263
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '1'	System	07 Oct 2020 17:30:17

US3012263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	14 Oct 2020 15:23:52

US3012263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '14 Oct 2020'	Tambra Dora (b) (4) (b) (4)	14 Oct 2020 15:23:52

US3012263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	14 Oct 2020 15:23:52

US3012263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Tambra Dora (b) (4) (b) (4)	14 Oct 2020 15:23:52

US3012263

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	14 Oct 2020 15:23:56

US3012263
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '1'	System	14 Oct 2020 15:23:56

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	21 Oct 2020 23:44:49

US3012263

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '21 Oct 2020'	Tambra Dora (b) (4) (b) (4)	21 Oct 2020 23:44:49

US3012263
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	21 Oct 2020 23:44:49

US3012263
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Tambra Dora (b) (4) (b) (4)	21 Oct 2020 23:44:49

FDA-CBER-2022-1614-0012489

US3012263

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	21 Oct 2020 23:44:53

US3012263
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '1'	System	21 Oct 2020 23:44:53

US3012263
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:29

US3012263
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '30 Oct 2020'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:29

US3012263

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:47

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 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Clinic (Clinic)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:29

US3012263
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'VISIT3'	System	31 Oct 2020 00:05:29

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '30 Oct 2020'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '15:55'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '30 Oct 2020 15:55'	System	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '98.3' F	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Oral (Oral)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '97'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'bpm'	System	31 Oct 2020 00:05:56

US3012263
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '16'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'breaths/min'	System	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '139'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'mmHg'	System	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '82'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered 'mmHg'	System	31 Oct 2020 00:05:56

US3012263
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51

US3012263
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'No (N)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:06:07

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US3012263

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:47

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered empty.	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:06:07

US3012263

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:07:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '30 Oct 2020'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:07:24

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered '16:07'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:07:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '30 Oct 2020 16:07'	System	31 Oct 2020 00:07:24

FDA-CBER-2022-1614-0012518

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:52:44
User entered 'Yes (Y)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:07:28

FDA-CBER-2022-1614-0012519

US3012263
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '1'	System	31 Oct 2020 00:07:28

US3012263
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 64'	System	02 Sep 2020 22:57:31

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please 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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

FDA-CBER-2022-1614-0012531

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please 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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please 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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04
Data entry locked.	System	02 Sep 2020 22:57:31
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 22:57:31

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04
Data entry locked.	System	02 Sep 2020 22:57:31
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 71'	System	02 Sep 2020 22:57:31

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please 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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please 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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please 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)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04
Data entry locked.	System	02 Sep 2020 22:57:31
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 22:57:31

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:04
Data entry locked.	System	02 Sep 2020 22:57:31
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 78'	System	02 Sep 2020 22:57:31

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-17T13:00:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered 'Yes (Y)'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-17T13:00:49', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered 'No (N)'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-17T13:00:56', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered 'No (N)'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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)	03 Apr 2021 16:12:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-17T13:01:12', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered 'Yes (Y)'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please 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)	03 Apr 2021 16:12:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-17T13:01:20', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-17T13:01:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered '17 Nov 2020 13:01:30'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
Data entry locked.	System	02 Sep 2020 22:57:31
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 22:57:31

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:12:01
Data entry locked.	System	02 Sep 2020 22:57:31
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 22:57:31

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-11-23T10:30:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0e097370-0dcf-4831-8880-d6c9440e7289'	System	23 Nov 2020 16:30:27
User entered 'No (N)'	System	23 Nov 2020 16:30:27

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-11-23T10:30:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0e097370-0dcf-4831-8880-d6c9440e7289'	System	23 Nov 2020 16:30:27
User entered 'No (N)'	System	23 Nov 2020 16:30:27

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-23T10:30:24', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0e097370-0dcf-4831-8880-d6c9440e7289'	System	23 Nov 2020 16:30:27
User entered '23 Nov 2020 10:30:24'	System	23 Nov 2020 16:30:27

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-11-28T20:10:06', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1151617f-9ec3-4d80-97d9-7aea80d95e62'	System	29 Nov 2020 02:10:17
User entered 'No (N)'	System	29 Nov 2020 02:10:17

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-11-28T20:10:09', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1151617f-9ec3-4d80-97d9-7aea80d95e62'	System	29 Nov 2020 02:10:17
User entered 'No (N)'	System	29 Nov 2020 02:10:17

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-28T20:10:15', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1151617f-9ec3-4d80-97d9-7aea80d95e62'	System	29 Nov 2020 02:10:17
User entered '28 Nov 2020 20:10:15'	System	29 Nov 2020 02:10:17

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-12-04T06:17:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '7f0b0bdd-e75d-48cd-ab42-b09b7f7df08c'	System	04 Dec 2020 12:17:58
User entered 'No (N)'	System	04 Dec 2020 12:17:58

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-12-04T06:17:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '7f0b0bdd-e75d-48cd-ab42-b09b7f7df08c'	System	04 Dec 2020 12:17:58
User entered 'No (N)'	System	04 Dec 2020 12:17:58

FDA-CBER-2022-1614-0012600

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-12-04T06:17:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '7f0b0bdd-e75d-48cd-ab42-b09b7f7df08c'	System	04 Dec 2020 12:17:58
User entered '04 Dec 2020 06:17:57'	System	04 Dec 2020 12:17:58

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-12-11T05:12:02', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'daf1942f-f820-432c-b6da-5c49d5b67013'	System	11 Dec 2020 11:12:20
User entered 'No (N)'	System	11 Dec 2020 11:12:20

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-12-11T05:12:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'daf1942f-f820-432c-b6da-5c49d5b67013'	System	11 Dec 2020 11:12:20
User entered 'No (N)'	System	11 Dec 2020 11:12:20

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-12-11T05:12:17', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'daf1942f-f820-432c-b6da-5c49d5b67013'	System	11 Dec 2020 11:12:20
User entered '11 Dec 2020 05:12:17'	System	11 Dec 2020 11:12:20

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-12-18T05:33:01', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'aaf0dfa8-3749-41b5-ae4e-7ac067ba737c'	System	18 Dec 2020 11:33:15
User entered 'No (N)'	System	18 Dec 2020 11:33:15

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-12-18T05:33:07', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'aaf0dfa8-3749-41b5-ae4e-7ac067ba737c'	System	18 Dec 2020 11:33:15
User entered 'No (N)'	System	18 Dec 2020 11:33:15

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-12-18T05:33:12', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'aaf0dfa8-3749-41b5-ae4e-7ac067ba737c'	System	18 Dec 2020 11:33:15
User entered '18 Dec 2020 05:33:12'	System	18 Dec 2020 11:33:15

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-12-26T10:47:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '046b6792-594b-4269-aae3-c57a74b4330e'	System	26 Dec 2020 16:47:48
User entered 'No (N)'	System	26 Dec 2020 16:47:48

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2020-12-26T10:47:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '046b6792-594b-4269-aae3-c57a74b4330e'	System	26 Dec 2020 16:47:48
User entered 'No (N)'	System	26 Dec 2020 16:47:48

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-12-26T10:47:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '046b6792-594b-4269-aae3-c57a74b4330e'	System	26 Dec 2020 16:47:48
User entered '26 Dec 2020 10:47:44'	System	26 Dec 2020 16:47:48

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-01-01T00:28:27', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e416f60b-5983-4db8-87af-e70cddc76596'	System	01 Jan 2021 06:28:44
User entered 'No (N)'	System	01 Jan 2021 06:28:44

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-01-01T00:28:31', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e416f60b-5983-4db8-87af-e70cddc76596'	System	01 Jan 2021 06:28:44
User entered 'No (N)'	System	01 Jan 2021 06:28:44

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-01-01T00:28:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e416f60b-5983-4db8-87af-e70cddc76596'	System	01 Jan 2021 06:28:44
User entered '01 Jan 2021 00:28:39'	System	01 Jan 2021 06:28:44

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:58:04

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-01-08T05:44:28', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'af1f51f4-69c9-4ec9-9691-f7515535ebc2'	System	08 Jan 2021 11:44:39
User entered 'No (N)'	System	08 Jan 2021 11:44:39

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-01-08T05:44:32', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'af1f51f4-69c9-4ec9-9691-f7515535ebc2'	System	08 Jan 2021 11:44:39
User entered 'No (N)'	System	08 Jan 2021 11:44:39

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-01-08T05:44:37', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'af1f51f4-69c9-4ec9-9691-f7515535ebc2'	System	08 Jan 2021 11:44:39
User entered '08 Jan 2021 05:44:37'	System	08 Jan 2021 11:44:39

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:58:04

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US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-01-15T05:52:12', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'fa82646a-bd53-4ccb-868b-b993bda6c778'	System	15 Jan 2021 11:52:24
User entered 'No (N)'	System	15 Jan 2021 11:52:24

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-01-15T05:52:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'fa82646a-bd53-4ccb-868b-b993bda6c778'	System	15 Jan 2021 11:52:24
User entered 'No (N)'	System	15 Jan 2021 11:52:24

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-01-15T05:52:21', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'fa82646a-bd53-4ccb-868b-b993bda6c778'	System	15 Jan 2021 11:52:24
User entered '15 Jan 2021 05:52:21'	System	15 Jan 2021 11:52:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:58:04

FDA-CBER-2022-1614-0012638

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-01-22T06:30:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '7dc88fbc-3438-4547-abdb-a7644ac061be'	System	22 Jan 2021 12:30:23
User entered 'No (N)'	System	22 Jan 2021 12:30:23

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-01-22T06:30:17', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '7dc88fbc-3438-4547-abdb-a7644ac061be'	System	22 Jan 2021 12:30:23
User entered 'No (N)'	System	22 Jan 2021 12:30:23

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-01-22T06:30:21', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '7dc88fbc-3438-4547-abdb-a7644ac061be'	System	22 Jan 2021 12:30:23
User entered '22 Jan 2021 06:30:21'	System	22 Jan 2021 12:30:23

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-01-29T10:16:28', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6f39b031-c03b-4cfc-a668-0b9e96dba81c'	System	29 Jan 2021 16:16:58
User entered 'No (N)'	System	29 Jan 2021 16:16:58

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-01-29T10:16:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6f39b031-c03b-4cfc-a668-0b9e96dba81c'	System	29 Jan 2021 16:16:58
User entered 'Yes (Y)'	System	29 Jan 2021 16:16:58

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Please 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 (925f6005fee9c9e7)', Time: '2021-01-29T10:16:45', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6f39b031-c03b-4cfc-a668-0b9e96dba81c'	System	29 Jan 2021 16:16:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Jan 2021 16:16:58

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-01-29T10:16:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6f39b031-c03b-4cfc-a668-0b9e96dba81c'	System	29 Jan 2021 16:16:58
User entered '29 Jan 2021 10:16:48'	System	29 Jan 2021 16:16:58

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-02-05T10:34:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1be01dbd-475e-459c-8d6e-8569973b58f0'	System	05 Feb 2021 16:34:16
User entered 'No (N)'	System	05 Feb 2021 16:34:16

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-02-05T10:34:09', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1be01dbd-475e-459c-8d6e-8569973b58f0'	System	05 Feb 2021 16:34:16
User entered 'No (N)'	System	05 Feb 2021 16:34:16

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-02-05T10:34:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1be01dbd-475e-459c-8d6e-8569973b58f0'	System	05 Feb 2021 16:34:16
User entered '05 Feb 2021 10:34:13'	System	05 Feb 2021 16:34:16

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:58:04

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-02-12T04:36:25', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61d18375-3de1-4d51-9421-e9deafbeaf64'	System	12 Feb 2021 10:36:38
User entered 'No (N)'	System	12 Feb 2021 10:36:38

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-02-12T04:36:32', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61d18375-3de1-4d51-9421-e9deafbeaf64'	System	12 Feb 2021 10:36:38
User entered 'No (N)'	System	12 Feb 2021 10:36:38

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-02-12T04:36:35', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61d18375-3de1-4d51-9421-e9deafbeaf64'	System	12 Feb 2021 10:36:38
User entered '12 Feb 2021 04:36:35'	System	12 Feb 2021 10:36:38

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:58:04

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:58:04

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US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-02-19T03:15:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c6e2e6f0-6807-4db8-9b9e-9d77dce5d4c6'	System	19 Feb 2021 09:16:08
User entered 'No (N)'	System	19 Feb 2021 09:16:08

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-02-19T03:15:56', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c6e2e6f0-6807-4db8-9b9e-9d77dce5d4c6'	System	19 Feb 2021 09:16:08
User entered 'No (N)'	System	19 Feb 2021 09:16:08

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-02-19T03:16:01', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c6e2e6f0-6807-4db8-9b9e-9d77dce5d4c6'	System	19 Feb 2021 09:16:08
User entered '19 Feb 2021 03:16:01'	System	19 Feb 2021 09:16:08

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-02-26T03:04:42-06:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1ea871e4-6d81-4705-bf60-5601acb961f8'	System	26 Feb 2021 09:04:52
User entered 'No (N)'	System	26 Feb 2021 09:04:52

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-02-26T03:04:45-06:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1ea871e4-6d81-4705-bf60-5601acb961f8'	System	26 Feb 2021 09:04:52
User entered 'No (N)'	System	26 Feb 2021 09:04:52

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-02-26T03:04:49-06:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1ea871e4-6d81-4705-bf60-5601acb961f8'	System	26 Feb 2021 09:04:52
User entered '26 Feb 2021 03:04:49'	System	26 Feb 2021 09:04:52

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-03-05T16:39:15-06:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f315e522-99c2-4956-9698-52d6df4938a7'	System	05 Mar 2021 22:39:34
User entered 'No (N)'	System	05 Mar 2021 22:39:34

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-03-05T16:39:25-06:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f315e522-99c2-4956-9698-52d6df4938a7'	System	05 Mar 2021 22:39:34
User entered 'No (N)'	System	05 Mar 2021 22:39:34

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-03-05T16:39:30-06:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f315e522-99c2-4956-9698-52d6df4938a7'	System	05 Mar 2021 22:39:34
User entered '05 Mar 2021 16:39:30'	System	05 Mar 2021 22:39:34

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:58:04

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-03-12T04:48:29-06:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6e34f811-4271-4d13-bed8-9c17e32321d5'	System	12 Mar 2021 10:48:39
User entered 'No (N)'	System	12 Mar 2021 10:48:39

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-03-12T04:48:34-06:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6e34f811-4271-4d13-bed8-9c17e32321d5'	System	12 Mar 2021 10:48:39
User entered 'No (N)'	System	12 Mar 2021 10:48:39

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-03-12T04:48:37-06:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6e34f811-4271-4d13-bed8-9c17e32321d5'	System	12 Mar 2021 10:48:39
User entered '12 Mar 2021 04:48:37'	System	12 Mar 2021 10:48:39

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-03-19T12:46:44-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e6f17dae-d959-4a2e-a8f6-bd02303ab854'	System	19 Mar 2021 17:46:58
User entered 'No (N)'	System	19 Mar 2021 17:46:58

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-03-19T12:46:48-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e6f17dae-d959-4a2e-a8f6-bd02303ab854'	System	19 Mar 2021 17:46:58
User entered 'No (N)'	System	19 Mar 2021 17:46:58

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-03-19T12:46:52-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e6f17dae-d959-4a2e-a8f6-bd02303ab854'	System	19 Mar 2021 17:46:58
User entered '19 Mar 2021 12:46:52'	System	19 Mar 2021 17:46:58

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:58:04

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-03-26T03:45:55-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '34e96ea2-8814-45f9-a10b-5f2382f39333'	System	26 Mar 2021 08:46:09
User entered 'No (N)'	System	26 Mar 2021 08:46:09

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-03-26T03:46:00-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '34e96ea2-8814-45f9-a10b-5f2382f39333'	System	26 Mar 2021 08:46:09
User entered 'No (N)'	System	26 Mar 2021 08:46:09

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-03-26T03:46:03-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '34e96ea2-8814-45f9-a10b-5f2382f39333'	System	26 Mar 2021 08:46:09
User entered '26 Mar 2021 03:46:03'	System	26 Mar 2021 08:46:09

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-04-02T03:07:36-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'd3961566-3c7b-4008-bf1c-664f19d1f645'	System	02 Apr 2021 08:07:50
User entered 'No (N)'	System	02 Apr 2021 08:07:50

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-04-02T03:07:41-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'd3961566-3c7b-4008-bf1c-664f19d1f645'	System	02 Apr 2021 08:07:50
User entered 'No (N)'	System	02 Apr 2021 08:07:50

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-04-02T03:07:44-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'd3961566-3c7b-4008-bf1c-664f19d1f645'	System	02 Apr 2021 08:07:50
User entered '02 Apr 2021 03:07:44'	System	02 Apr 2021 08:07:50

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-04-09T03:44:41-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '72ded272-8b6b-4b68-9287-83862788d76b'	System	09 Apr 2021 08:44:51
User entered 'No (N)'	System	09 Apr 2021 08:44:51

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-04-09T03:44:46-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '72ded272-8b6b-4b68-9287-83862788d76b'	System	09 Apr 2021 08:44:51
User entered 'No (N)'	System	09 Apr 2021 08:44:51

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-04-09T03:44:49-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '72ded272-8b6b-4b68-9287-83862788d76b'	System	09 Apr 2021 08:44:51
User entered '09 Apr 2021 03:44:49'	System	09 Apr 2021 08:44:51

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-04-16T03:44:50-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'cfa28806-66fa-4505-94bd-485b7a4f5c96'	System	16 Apr 2021 08:45:00
User entered 'No (N)'	System	16 Apr 2021 08:45:00

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-04-16T03:44:54-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'cfa28806-66fa-4505-94bd-485b7a4f5c96'	System	16 Apr 2021 08:45:00
User entered 'No (N)'	System	16 Apr 2021 08:45:00

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-04-16T03:44:57-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'cfa28806-66fa-4505-94bd-485b7a4f5c96'	System	16 Apr 2021 08:45:00
User entered '16 Apr 2021 03:44:57'	System	16 Apr 2021 08:45:00

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-04-24T15:54:21-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '96905a80-9c05-4605-92e2-0beb3e8811f9'	System	24 Apr 2021 20:54:32
User entered 'No (N)'	System	24 Apr 2021 20:54:32

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-04-24T15:54:26-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '96905a80-9c05-4605-92e2-0beb3e8811f9'	System	24 Apr 2021 20:54:32
User entered 'No (N)'	System	24 Apr 2021 20:54:32

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-04-24T15:54:28-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '96905a80-9c05-4605-92e2-0beb3e8811f9'	System	24 Apr 2021 20:54:32
User entered '24 Apr 2021 15:54:28'	System	24 Apr 2021 20:54:32

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:58:04

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-04-30T02:31:00-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '7a01cecf-139a-4f48-9862-3a09be3fb6b3'	System	30 Apr 2021 07:31:13
User entered 'No (N)'	System	30 Apr 2021 07:31:13

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

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 (925f6005fee9c9e7)', Time: '2021-04-30T02:31:04-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '7a01cecf-139a-4f48-9862-3a09be3fb6b3'	System	30 Apr 2021 07:31:13
User entered 'No (N)'	System	30 Apr 2021 07:31:13

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-04-30T02:31:08-05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '7a01cecf-139a-4f48-9862-3a09be3fb6b3'	System	30 Apr 2021 07:31:13
User entered '30 Apr 2021 02:31:08'	System	30 Apr 2021 07:31:13

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:58:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:58:04

FDA-CBER-2022-1614-0012738

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:58:04

FDA-CBER-2022-1614-0012749

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:58:04

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:58:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:58:04

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:58:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:58:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:58:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:58:04

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:58:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:58:04

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US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:58:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:58:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:58:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:58:04

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US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:58:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:58:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:58:04

FDA-CBER-2022-1614-0012905

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:58:04

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:58:04

FDA-CBER-2022-1614-0012911

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:58:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:58:04

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:58:04

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:58:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:58:04

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US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:58:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:58:04

FDA-CBER-2022-1614-0012959

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:58:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:58:04

FDA-CBER-2022-1614-0012962

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:48:47
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:48:47

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)	24 Apr 2021 10:50:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-03-02T06:49:25-06:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '04ef3ea3-d66d-4972-8273-248d26961a45'	System	02 Mar 2021 12:49:36
User entered 'No (N)'	System	02 Mar 2021 12:49:36

US3012263

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:48:47

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:50:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2021-03-02T06:49:33-06:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '04ef3ea3-d66d-4972-8273-248d26961a45'	System	02 Mar 2021 12:49:36
User entered '02 Mar 2021 06:49:33'	System	02 Mar 2021 12:49:36

US3012263

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:33:17
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	11 Dec 2020 18:57:30

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:33:17
User entered '25 Nov 2020'	Pamela Fidler (b) (4)	11 Dec 2020 18:57:30

FDA-CBER-2022-1614-0012971

Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:33:17
User entered 'Contact Made (CONTACT MADE)'	Pamela Fidler (b) (4)	11 Dec 2020 18:57:30

FDA-CBER-2022-1614-0012972

US3012263

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:33:17
User entered empty.	Pamela Fidler (b) (4)	11 Dec 2020 18:57:30

US3012263

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:33:17
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	11 Dec 2020 18:57:32

US3012263
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:51
User entered '1'	System	11 Dec 2020 18:57:32

US3012263

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
User entered 'Yes (Y)'	Jessica Ruff (b) (4)	30 Dec 2020 00:51:13
	(b) (4)	

US3012263

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '29 Dec 2020'	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:51:13

US3012263

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Contact Made (CONTACT MADE)'	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:51:13

US3012263

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:51:13

US3012263

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:51:19

US3012263
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User entered '1'	System	30 Dec 2020 00:51:19

US3012263

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	26 Jan 2021 22:14:54

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '26 Jan 2021'	Dean Skiles (b) (4) (b) (4)	26 Jan 2021 22:14:54

US3012263

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Contact Made (CONTACT MADE)'	Dean Skiles (b) (4) (b) (4)	26 Jan 2021 22:14:54

US3012263
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Dean Skiles (b) (4) (b) (4)	26 Jan 2021 22:14:54

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	26 Jan 2021 22:14:59

US3012263
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User entered '1'	System	26 Jan 2021 22:14:59

US3012263
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jessica Ruff (b) (4) (b) (4)	27 Feb 2021 01:34:07

US3012263

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '26 Feb 2021'	Jessica Ruff (b) (4) (b) (4)	27 Feb 2021 01:34:07

US3012263

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Contact Made (CONTACT MADE)'	Jessica Ruff (b) (4) (b) (4)	27 Feb 2021 01:34:07

US3012263

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jessica Ruff (b) (4) (b) (4)	27 Feb 2021 01:34:07

US3012263
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jessica Ruff (b) (4) (b) (4)	27 Feb 2021 01:34:10

US3012263
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:19:34
User entered '1'	System	27 Feb 2021 01:34:10

US3012263
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered '29 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:43:06

US3012263
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	29 Mar 2021 20:43:12
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Mar 2021 20:43:12
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	29 Mar 2021 20:43:06
User entered empty.	Pamela Fidler (b) (4)	29 Mar 2021 20:43:06

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User entered 'VISIT4'	System	29 Mar 2021 20:43:06

US3012263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:31

US3012263
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered '29 Mar 2021'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:31

US3012263
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered '14:16'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:31

US3012263
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User entered '29 Mar 2021 14:16'	System	29 Mar 2021 20:43:31

US3012263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '99.1' F	Pamela Fidler (b) (4)	29 Mar 2021 20:43:31

US3012263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered 'Oral (Oral)'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:31

US3012263
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered empty.	Pamela Fidler (b) (4)	29 Mar 2021 20:43:31

US3012263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered '95'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:31

US3012263
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User entered 'bpm'	System	29 Mar 2021 20:43:31

US3012263
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered '18'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:31

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User entered 'breaths/min'	System	29 Mar 2021 20:43:31

FDA-CBER-2022-1614-0013008

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered '138'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:31

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User entered 'mmHg'	System	29 Mar 2021 20:43:31

FDA-CBER-2022-1614-0013010

US3012263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '90'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:31

US3012263
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User entered 'mmHg'	System	29 Mar 2021 20:43:31

US3012263
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18

US3012263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18

US3012263

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:35

US3012263

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:47

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
	(b) (4)	
User entered '29 Mar 2021'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:35

US3012263

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:42

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered '29 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 20:43:42

FDA-CBER-2022-1614-0013018

US3012263
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:48:47

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Mar 2021 20:43:46
User entered '14:42' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Mar 2021 20:43:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Mar 2021 20:43:42
User entered '14:4' (non-conformant).	Pamela Fidler (b) (4)	29 Mar 2021 20:43:42

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User entered '29 Mar 2021 14:42'	System	29 Mar 2021 20:43:46
User entered '29 Mar 2021 14:4' (non-conformant).	System	29 Mar 2021 20:43:42

FDA-CBER-2022-1614-0013020

US3012263

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	29 Mar 2021 20:43:47

US3012263
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:18
User entered '1'	System	29 Mar 2021 20:43:47

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:47

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 21:18:36

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:18:36

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:47

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 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Jan 2021 21:18:36

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:47

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 21:18:36

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:47

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:47

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 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	09 Apr 2021 20:45:06
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	08 Apr 2021 19:42:58
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:05:57

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:47

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:47

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:50:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	09 Apr 2021 20:45:06
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	08 Apr 2021 19:43:02
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jennifer Leyva (b) (4) (b) (4)	08 Apr 2021 19:42:58
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 19:04:10
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:05:57

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:47

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:47

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:47

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 04:03:56
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:47

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 04:03:56
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:47

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:47

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '1'	System	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:47

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '1'	System	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '66.0' in	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '184.6' lb	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:48:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '29.85752'	System	19 Jan 2021 21:20:44
DataPoint set to visible.	System	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '66.0' in	(b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '184.6' lb	(b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '29.85752'	System	19 Jan 2021 21:20:44
DataPoint set to visible.	System	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '08:33'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '19 Jan 2021 08:33'	System	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '98.7' F	(b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '94'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'bpm'	System	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'breaths/min'	System	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
User entered '132'	(b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'mmHg'	System	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
User entered '82'	(b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'mmHg'	System	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '66.0' in	(b) (4), (b) (6)	19 Jan 2021 21:20:44

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '184.6' lb	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:20:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '29.85752'	System	19 Jan 2021 21:20:44
DataPoint set to visible.	System	19 Jan 2021 21:19:16

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:22:18

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '10:20'	(b) (4), (b) (6)	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '19 Jan 2021 10:20'	System	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '98.9' F	(b) (4), (b) (6)	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '75'	(b) (4), (b) (6)	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'bpm'	System	19 Jan 2021 21:22:18

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:22:18

FDA-CBER-2022-1614-0013073

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'breaths/min'	System	19 Jan 2021 21:22:18

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '150'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'mmHg'	System	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '96'	(b) (4), (b) (6)	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'mmHg'	System	19 Jan 2021 21:22:18

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 21:23:41

Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:48:47

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 21:23:41

FDA-CBER-2022-1614-0013080

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 21:24:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 21:24:17

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 21:24:17

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'mRNA-1273'	System	19 Jan 2021 21:24:17
DataPoint set to visible.	System	19 Jan 2021 21:19:16

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 21:24:17

FDA-CBER-2022-1614-0013085

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '09:46'	(b) (4), (b) (6)	19 Jan 2021 21:24:17

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '19 Jan 2021 09:46'	System	19 Jan 2021 21:24:17

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	19 Jan 2021 21:24:17

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'ONCE'	System	19 Jan 2021 21:24:17

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 21:24:17

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 21:24:36

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 21:24:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '08:55'	(b) (4), (b) (6)	19 Jan 2021 21:24:36

FDA-CBER-2022-1614-0013093

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '19 Jan 2021 08:55'	System	19 Jan 2021 21:24:36

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:24:46

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:48:47

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 21:24:46

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:48:47

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '08:51'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:24:46

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:48:47

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '19 Jan 2021 08:51'	System	19 Jan 2021 21:24:46

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:24:49

US3012263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '1'	System	19 Jan 2021 21:24:49

US3012263
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	26 Jan 2021 22:13:46

US3012263

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '26 Jan 2021'	Dean Skiles (b) (4) (b) (4)	26 Jan 2021 22:13:46

US3012263
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Contact Made (CONTACT MADE)'	Dean Skiles (b) (4) (b) (4)	26 Jan 2021 22:13:46

US3012263

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
User entered empty.	Dean Skiles (b) (4)	26 Jan 2021 22:13:46
	(b) (4)	

US3012263

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Dean Skiles (b) (4) (b) (4)	26 Jan 2021 22:13:53

US3012263
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '1'	System	26 Jan 2021 22:13:53

US3012263
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '1'	System	26 Jan 2021 22:13:53
DataPoint set to visible.	System	26 Jan 2021 22:13:53

US3012263
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:19

US3012263

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '01 Mar 2021'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:19

US3012263

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:47

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 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:19

US3012263
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'OLD29'	System	02 Mar 2021 01:01:19

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '01 Mar 2021'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '13:20'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '01 Mar 2021 13:20'	System	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '98.4' F	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:36

US3012263
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:48:47
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:36

US3012263
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:48:47

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '86'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:36

US3012263
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:48:47
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'bpm'	System	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '16'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'breaths/min'	System	02 Mar 2021 01:01:36

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '139'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'mmHg'	System	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '89'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'mmHg'	System	02 Mar 2021 01:01:36

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:59

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:59

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '01 Mar 2021'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:59

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '15:31'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:59

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '01 Mar 2021 15:31'	System	02 Mar 2021 01:01:59

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '99.4' F	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:59

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:59

US3012263
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:48:47
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:59

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '86'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:59

FDA-CBER-2022-1614-0013136

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'bpm'	System	02 Mar 2021 01:01:59

FDA-CBER-2022-1614-0013137

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '16'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:59

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'breaths/min'	System	02 Mar 2021 01:01:59

FDA-CBER-2022-1614-0013139

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '152'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:01:59

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'mmHg'	System	02 Mar 2021 01:01:59

US3012263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '98'	Jennifer Leyva (b) (4)	02 Mar 2021 01:01:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'mmHg'	System	02 Mar 2021 01:01:59

FDA-CBER-2022-1614-0013143

US3012263

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:47

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:02:07

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '01 Mar 2021'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:02:07

US3012263
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:48:47

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:02:21

US3012263
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:48:47
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:02:21

US3012263

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:02:21

US3012263
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:48:47

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'mRNA-1273'	System	02 Mar 2021 01:02:21
DataPoint set to visible.	System	26 Jan 2021 22:13:53

US3012263

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:47

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '01 Mar 2021'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:02:21

US3012263
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:48:47

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '14:50'	Jennifer Leyva (b) (4)	02 Mar 2021 01:02:21

US3012263
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:48:47

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '01 Mar 2021 14:50'	System	02 Mar 2021 01:02:21

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:02:21

FDA-CBER-2022-1614-0013153

US3012263
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:48:47
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'ONCE'	System	02 Mar 2021 01:02:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 01:02:21

FDA-CBER-2022-1614-0013155

US3012263
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Mar 2021 01:02:23

US3012263

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '1'	System	02 Mar 2021 01:02:23

US3012263
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:48:47

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 19:23:00

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '8 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 19:23:00

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Mar 2021 19:23:00

US3012263

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:47

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:23:00

US3012263

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 19:23:07

US3012263

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:47

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:32:08
User entered '1'	System	08 Mar 2021 19:23:07

US3012263
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	29 Mar 2021 20:41:52

US3012263
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '29 Mar 2021'	Pamela Fidler (b) (4)	29 Mar 2021 20:41:52

US3012263
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered 'Clinic (Clinic)'	Pamela Fidler (b) (4)	29 Mar 2021 20:41:52

US3012263
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:48:47
Folder OID

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Mar 2021 20:41:52

US3012263

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:11

US3012263

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '29 Mar 2021'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:11

US3012263
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '14:16'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:11

US3012263
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '29 Mar 2021 14:16'	System	29 Mar 2021 20:42:11

US3012263
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '99.1' F	Pamela Fidler (b) (4)	29 Mar 2021 20:42:11

US3012263

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered 'Oral (Oral)'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:11

US3012263
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered empty.	Pamela Fidler (b) (4)	29 Mar 2021 20:42:11

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '95'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:11

FDA-CBER-2022-1614-0013175

US3012263
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Mar 2021 20:42:11

US3012263

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '18'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:11

US3012263

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Mar 2021 20:42:11

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '138'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:11

FDA-CBER-2022-1614-0013179

US3012263
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:42:11

US3012263

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '90'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:11

US3012263
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:42:11

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:20

FDA-CBER-2022-1614-0013183

US3012263

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:47

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '29 Mar 2021'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:20

US3012263

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	08 Apr 2021 14:58:14
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:30

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '29 Mar 2021'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:30

US3012263

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:58:14
User entered '14:42'	Pamela Fidler (b) (4)	29 Mar 2021 20:42:30

US3012263

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:47

Collection date and time (derived)

Audit	User	Time (GMT)
User entered '29 Mar 2021 14:42'	System	29 Mar 2021 20:42:30

US3012263
Folder: Unscheduled 19 Jan 2021
Form: Unscheduled Visit Assessment
Generated On: 09 Jun 2021 14:48:47
Visit Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:22:45

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 14:48:47

Physical Exam

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 21:22:45

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 14:48:47

Vital Signs

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '1'	(b) (4), (b) (6)	19 Jan 2021 21:22:45

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 14:48:47

Immunogenicity Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 21:22:45

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 14:48:47

Pregnancy Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 21:22:45

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 21:23:20

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:23:20

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '10:22'	(b) (4), (b) (6)	19 Jan 2021 21:23:20

US3012263
Folder: Unscheduled 19 Jan 2021
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User entered '19 Jan 2021 10:22'	System	19 Jan 2021 21:23:20

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:23:20

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:23:20

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 21:23:20

FDA-CBER-2022-1614-0013200

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Jan 2021 21:23:20

FDA-CBER-2022-1614-0013201

US3012263
Folder: Unscheduled 19 Jan 2021
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User entered 'bpm'	System	19 Jan 2021 21:23:20

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:23:20

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User entered 'breaths/min'	System	19 Jan 2021 21:23:20

US3012263
Folder: Unscheduled 19 Jan 2021
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '122'	(b) (4), (b) (6)	19 Jan 2021 21:23:20

US3012263

Folder: Unscheduled 19 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:47

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User entered 'mmHg'	System	19 Jan 2021 21:23:20

US3012263
Folder: Unscheduled 19 Jan 2021
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '88'	(b) (4), (b) (6)	19 Jan 2021 21:23:20

US3012263
Folder: Unscheduled 19 Jan 2021
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50
User entered 'mmHg'	System	19 Jan 2021 21:23:20

US3012263
Folder: Unscheduled 19 Jan 2021
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50

US3012263
Folder: Unscheduled 19 Jan 2021
Form: Vital Signs
Generated On: 09 Jun 2021 14:48:47
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:37:50

US3012263

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:48:47

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:24
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:10:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Katherine Davis (b) (4)	16 Sep 2020 20:21:21
User entered 'No (N)'	Jennifer Leyva (b) (4)	02 Sep 2020 22:31:42

US3012263
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:48:47
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query '" Fire in AE page: AE #1 LOOSE MOLAR Per DM CLR: Other Action Taken = None. However, Con Med AMOXICILIN is recorded within the same timeframe which may be associated with this AE condition. Kindly review and confirm if the response to 'Other Action Taken' should be updated to 'Concomitant Medication'. Update if applicable. Otherwise, provide a comment." ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:36:15
Query '" Fire in AE page: AE #1 LOOSE MOLAR Per DM CLR: Other Action Taken = None. However, Con Med AMOXICILIN is recorded within the same timeframe which may be associated with this AE condition. Kindly review and confirm if the response to 'Other Action Taken' should be updated to 'Concomitant Medication'. Update if applicable. Otherwise, provide a comment." ' answered with 'Con-Procedure performed. Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	04 Dec 2020 19:41:25
User opened query '" Fire in AE page: AE #1 LOOSE MOLAR Per DM CLR: Other Action Taken = None. However, Con Med AMOXICILIN is recorded within the same timeframe which may be associated with this AE condition. Kindly review and confirm if the response to 'Other Action Taken' should be updated to 'Concomitant Medication'. Update if applicable. Otherwise, provide a comment." ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 02:37:37

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental disorders NEC, PT: Loose tooth, LLT: Loose tooth - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:05:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:05:58
Data point term sent to Coder	System	16 Sep 2020 20:33:07
User entered 'LOOSE MOLAR' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Sep 2020 20:32:51
Data point term sent to Coder	System	16 Sep 2020 20:22:47
User entered 'lose molar'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:48:47
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '15 Sep 2020'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Sep 2020 20:32:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Sep 2020 20:32:51
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Sep 2020 20:32:51
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'start time unk ' (Site from System).	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:27:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Sep 2020 20:27:33
User entered 'un:un' (non-conformant).	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:27:33
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Sep 2020 20:22:42
User entered '00:00'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User entered empty.	System	16 Sep 2020 20:32:51
User entered '15 Sep 2020 UN:UN' (non-conformant).	System	16 Sep 2020 20:27:33
User entered '15 Sep 2020 00:00'	System	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 15:22:28
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	25 Nov 2020 18:13:04
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	25 Nov 2020 18:12:56
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 02:30:59
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '16 Sep 2020' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	25 Nov 2020 18:12:56
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User entered empty.	System	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Grade 1/Mild (Grade 1/Mild)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:48:47

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:27:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 20:27:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:27:33
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:22:42
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:27:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 20:27:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:27:33
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:22:42
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:27:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 20:27:33
User entered 'None (NONE)' reason for change: Data Entry Error	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:27:33
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:22:42
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	04 Dec 2020 19:41:15
User entered '1'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '1' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	04 Dec 2020 19:41:15
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	25 Nov 2020 18:12:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:48:47
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'MOLAR EXTRACTION DUE TO LOOSE MOLAR' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Sep 2020 20:33:09
User entered 'molar extraction due to lose molar'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User entered '0'	System	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09
User entered '1'	System	16 Sep 2020 20:22:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:47

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

AEID

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 15:40:59
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:39:50
User entered 'USA-US006-2020-mRNA-1273-P301000003'	System	12 Nov 2020 16:28:37
User entered 'New'	(b) (4), (b) (6)	12 Nov 2020 16:28:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Gun shot wound, LLT: Gun shot wound - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 03:32:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 03:32:39
Data point term sent to Coder	System	11 Nov 2020 22:42:04
User entered 'Gunshot wound, right shoulder and spine'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:35
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:48:47
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:39
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:42
User entered '08 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:41:43

US3012263
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:48:47
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:16:47
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	21 Dec 2020 14:00:03
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	21 Dec 2020 14:00:03
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:46
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:59:24
User closed query 'Per source, End Date is recorded as, 01Mar2021. Please verify with source, and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:59:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 15:22:26
Query 'Per source, End Date is recorded as, 01Mar2021. Please verify with source, and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Pamela Fidler (b) (4)	16 Apr 2021 15:06:38
Signature has been broken.	Pamela Fidler (b) (4)	16 Apr 2021 15:06:22
User entered '01 Mar 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	16 Apr 2021 15:06:22
User opened query 'Per source, End Date is recorded as, 01Mar2021. Please verify with source, and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:17:51
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:17:10
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:16:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 20:12:50
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	21 Dec 2020 14:00:24

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
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	21 Dec 2020 14:00:18
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	21 Dec 2020 14:00:18
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	21 Dec 2020 14:00:03
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	21 Dec 2020 14:00:03
User entered '15 Dec 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	21 Dec 2020 14:00:03
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:29:56
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Dec 2020 18:24:19
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' answered with 'Subject is still recovering. New baseline will not be reached in the near future. It is against site policy to leave AEs open without resolution in sight.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	17 Dec 2020 23:02:46

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:48:47

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 22:27:17
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 17:08:16
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' answered with 'To be updated when applicable. Against site policy to leave queries open that do not have an end in sight.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	16 Dec 2020 21:45:15
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:50:44
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. (AE2)' canceled (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:50:21
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. (AE2)' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:49:49
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 15:39:44

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Comment added 'Against site policy to leave queries open. Site will answer and close query at every re-issue.'.	Jennifer Leyva (b) (4) (b) (4)	10 Dec 2020 18:44:10
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' answered with 'To be updated, if applicable.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	10 Dec 2020 18:43:29
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 18:38:11
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 20:12:38
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'To be updated when applicable' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	08 Dec 2020 23:47:26
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:07:10
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 12:57:58
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Per PI, still recovering. End date to be updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	04 Dec 2020 19:41:49
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:08:56

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:25
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Per PI, will remain open until completely healed. No timeframe known.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:05:55
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:01:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:47
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:49
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Generated On: 09 Jun 2021 14:48:47

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:41:43

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Severity

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:51
User entered 'Grade 4 (Grade 4)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:48:47
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:53
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:48:47
Death

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:55
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:08
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
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)	16 Nov 2020 09:03:15
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:17
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 is currently hospitalized. Discharge date is unknown.' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:43:52
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	11 Nov 2020 22:41:43
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:32
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:12:39
User entered '09 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:12:39
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:22
User entered '08 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:30
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:43:43
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:11:14
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:10:24
User entered '15 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:10:24
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:01:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:25
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:48:47
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:26
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	11 Nov 2020 22:43:57
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	11 Nov 2020 22:43:57
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:43:57
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	11 Nov 2020 22:41:43
User entered 'Unknown (UNK)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:29
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:30
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:32
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

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Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:34
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:48:47
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:39
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:48:47
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:49
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:51
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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None

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:52
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:55
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:56
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:00
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 20:13:00
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	21 Dec 2020 14:00:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	21 Dec 2020 14:00:18
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:30:21
User closed query 'PV Query: Please provide the final outcome of the event, when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	20 Dec 2020 18:24:24
Query 'PV Query: Please provide the final outcome of the event, when available. Please leave query open until information is available.' answered with 'Subject is still recovering. New baseline will not be reached in the near future. It is against site policy to leave AEs open without resolution in sight.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	17 Dec 2020 23:02:49

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Outcome

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final outcome of the event, when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 22:27:01
User closed query 'PV Query: Please provide the final outcome of the event, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 17:08:09
Query 'PV Query: Please provide the final outcome of the event, when available. Please leave query open until information is available. ' answered with 'To be updated when applicable. Against site policy to leave queries open that do not have an end in sight.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	16 Dec 2020 21:45:18
User opened query 'PV Query: Please provide the final outcome of the event, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:50:13
User closed query 'PV Query: Please provide the final outcome of the event, when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 15:39:52
Query 'PV Query: Please provide the final outcome of the event, when available. Please leave query open until information is available.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	10 Dec 2020 18:43:14
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	10 Dec 2020 18:43:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	10 Dec 2020 18:43:06
User opened query 'PV Query: Please provide the final outcome of the event, when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 18:38:35
User closed query 'PV Query: Please provide the final outcome of the event, when available.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 20:12:29
Query 'PV Query: Please provide the final outcome of the event, when available.' answered with 'To be updated, as applicable' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	08 Dec 2020 23:47:38

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Outcome

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final outcome of the event, when available.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:07:22
User closed query 'PV Query: Please provide the final outcome of the event, when available.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 12:58:01
Query 'PV Query: Please provide the final outcome of the event, when available.' answered with 'To be updated if/when outcome changes' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	04 Dec 2020 19:42:17
User opened query 'PV Query: Please provide the final outcome of the event, when available.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:09:15
User closed query 'PV Query: Please provide the final outcome of the event, when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:34
Query 'PV Query: Please provide the final outcome of the event, when available.' answered with 'Will remain open/Not recovered until fully healed' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:11:31
User opened query 'PV Query: Please provide the final outcome of the event, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:01:59
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:09:00
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
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)	30 Nov 2020 19:33:17
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 'Sent via email to Safety_Moderna@iqvia.com' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	25 Nov 2020 21:59:41
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:57
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:54
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:49
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:11:43

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:48:47
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:11:39
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:11:35
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:01:51
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:01:43
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)	20 Nov 2020 19:01:15
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:00:51
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:09:08
User entered 'Subject reported being shot during an invasion/break in at his home. Subject was shot twice, once in the Right shoulder and the second pierced both lungs causing collapse and is currently lodged in subject's spine. Currently hospitalized.'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

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Folder: Adverse Events

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Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:47

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 22:41:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

AEID

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:39:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:47
User entered 'USA-US006-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	12 Nov 2020 16:29:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:28
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pneumothorax, LLT: Collapse of lung - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:33:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:33:38
Data point term sent to Coder	System	11 Nov 2020 22:43:04
User entered 'Bilateral Lung Collapse'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:36
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:39
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:41
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:43:52
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:12:55
User entered '09 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:12:55
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:42
User entered '08 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:42:27

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:48:47
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:43:54
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:06:30
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:06:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:45
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:53:05
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:43:55
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:32
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:06:30
User entered '15 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:06:30
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:03:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:49
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:51
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Severity

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:54
User entered 'Grade 4 (Grade 4)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:55
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:04
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:05
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
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)	16 Nov 2020 09:03:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:07
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 is currently hospitalized. Discharge date not known.' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:43:16
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	11 Nov 2020 22:42:27
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:08
User entered '08 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:53:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:46:48
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:39
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:06:30
User entered '15 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:06:30
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:03:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:10
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:11
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	11 Nov 2020 22:42:51
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	11 Nov 2020 22:42:51
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:51
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	11 Nov 2020 22:42:27
User entered 'Unknown (UNK)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Generated On: 09 Jun 2021 14:48:47

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:13
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:14
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:16
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:18
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:19
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:21
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:22
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Generated On: 09 Jun 2021 14:48:47

None

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:28
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:30
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:32
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'PV Query: Please provide the final outcome of the event, when available.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:35:58
Query 'Per source page, event is still ongoing. Please clarify. Please also ensure both events in this SAE have their outcomes reviewed and updated as medical records are obtained. ' canceled (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 19:03:36
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:03:35
User opened query 'Per source page, event is still ongoing. Please clarify. Please also ensure both events in this SAE have their outcomes reviewed and updated as medical records are obtained. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:48:14
Query 'PV Query: Please provide the final outcome of the event, when available.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:44
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:06:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:06:30
User opened query 'PV Query: Please provide the final outcome of the event, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:04:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:35
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:48:47
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 20:34:32
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:36:15
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'CMs entered' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:10:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:09:59
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:03:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:03:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Narrative

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 22:43:36
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 22:43:36
User entered 'SUBJECT REPORTED BEING SHOT DURING AN INVASION/BREAK IN AT HIS HOME. SUBJECT WAS SHOT TWICE, ONCE IN THE RIGHT SHOULDER AND THE SECOND PIERCED BOTH LUNGS CAUSING COLLAPSE AND IS CURRENTLY LODGED IN SUBJECT'S SPINE. CURRENTLY HOSPITALIZED.' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:43:36
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 22:42:27
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:47

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 22:42:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:02
Data point term sent to Coder	System	20 Nov 2020 18:59:28
User entered 'Post-Traumatic Anxiety'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:00:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 19:00:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:00:31
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 18:59:13
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:55
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:24:58
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:00
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '09 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:07
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:48:47

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 18:59:13

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:48:47
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Generated On: 09 Jun 2021 14:48:47

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:48:47
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:48:47
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 18:59:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:48:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 19:00:31

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Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:48:47
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26

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Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:48:47
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Per CDM, DM CLR re-query: Response "non urticarial" is noted. noted. Please update the adverse event name to reflect your response. Please also reconcile with the applicable Con Med entry (CM#16). Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:06:12
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:52:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:52:03
Data point term sent to Coder	System	22 Jan 2021 18:29:32
Query 'Per CDM, DM CLR re-query: Response "non urticarial" is noted. noted. Please update the adverse event name to reflect your response. Please also reconcile with the applicable Con Med entry (CM#16). Review and update as appropriate. ' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	22 Jan 2021 18:28:57
Coding entries removed.	Pamela Fidler (b) (4)	22 Jan 2021 18:28:50
User entered 'RASH, BACK AND BUTTOCKS non uticarial' reason for change: Data Entry Error	Pamela Fidler (b) (4)	22 Jan 2021 18:28:50
User closed query 'Per DM CLR: Please review AE and please update to specify whether Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 14:32:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Adverse event

Audit	User	Time (GMT)
User opened query 'Per CDM, DM CLR re-query: Response "non urticarial" is noted. noted. Please update the adverse event name to reflect your response. Please also reconcile with the applicable Con Med entry (CM#16). Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 14:32:11
Query 'Per DM CLR: Please review AE and please update to specify whether Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'non uticarial ' (Site from DM).	Pamela Fidler (b) (4)	21 Jan 2021 18:53:12
User opened query 'Per DM CLR: Please review AE and please update to specify whether Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Jan 2021 23:17:35
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:03
Data point term sent to Coder	System	20 Nov 2020 19:04:32
User entered 'Rash, back and buttocks'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:25:42
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:04:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 19:04:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:01
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:03:36
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:48:47
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '15 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:44
User entered '18 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

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AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
User entered empty.	System	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)' reason for change: New Information	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:50:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
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	30 Dec 2020 00:50:45
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	30 Dec 2020 00:50:45
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	30 Dec 2020 00:50:37
User entered '22 Nov 2020' reason for change: New Information	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:50:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
User entered empty.	System	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:48:47

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

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Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4)	20 Nov 2020 19:03:36

Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:48:47

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Form: Adverse Events (5)
Generated On: 09 Jun 2021 14:48:47

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Form: Adverse Events (5)

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

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Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:50:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
User entered '0'	System	20 Nov 2020 19:03:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:48:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26
User entered '1'	System	20 Nov 2020 19:04:01

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Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:26

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Form: Adverse Events (6)
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Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Fractured ribs - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:34:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:34:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Traumatic fracture, LLT: Traumatic fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:25:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:25:10
Data point term sent to Coder	System	20 Nov 2020 19:15:46
User entered 'COMPOUND FRACTURE, T4 AND T3 RIBS, secondary to gunshot wound' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:21
User entered 'Compound Fracture, T4 and T3 ribs'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:30
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:15:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 19:15:21
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:21
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:15:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '09 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:26:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:15:03

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Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:57:58
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'Confirmed with pt at last contact, still ongoing' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 22:47:47
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 08:06:03
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Generated On: 09 Jun 2021 14:48:47

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:15:03

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Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:59:42
User closed query 'Per source, severity of AE is recorded as, Severe (Grade 3). Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:59:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 15:22:26
Query 'Per source, severity of AE is recorded as, Severe (Grade 3). Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Pamela Fidler (b) (4)	16 Apr 2021 15:08:24
Signature has been broken.	Pamela Fidler (b) (4)	16 Apr 2021 15:08:09
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	16 Apr 2021 15:08:09
User opened query 'Per source, severity of AE is recorded as, Severe (Grade 3). Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:27:10
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	20 Nov 2020 19:23:25
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:15:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 19:15:21
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	20 Nov 2020 19:15:21
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:21
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:15:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:23:25
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:26
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:23:25
User entered '09 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:28
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:23:25
User entered '15 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:23:25
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 14:48:47
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:31
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:42
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:47
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:53
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:15:03
	(b) (4)	

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Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 14:48:47
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:59:51
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:26
Signature has been broken.	Pamela Fidler (b) (4)	16 Apr 2021 15:08:09
User entered '0' reason for change: Data Entry Error	Pamela Fidler (b) (4)	16 Apr 2021 15:08:09
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:27:57
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	28 Jan 2021 22:48:48
User entered '0'	Jennifer Leyva (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 14:48:47
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:59:50
User closed query 'Per source, Other Action Taken, is recorded as, ConMed. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:59:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 15:22:26
Query 'Per source, Other Action Taken, is recorded as, ConMed. Please verify and update EDC/source accordingly.' answered with 'Updated' (Site from CRA).	Pamela Fidler (b) (4)	16 Apr 2021 15:09:30
Signature has been broken.	Pamela Fidler (b) (4)	16 Apr 2021 15:08:09
User entered '1' reason for change: Data Entry Error	Pamela Fidler (b) (4)	16 Apr 2021 15:08:09
User opened query 'Per source, Other Action Taken, is recorded as, ConMed. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:28:30
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:58:09
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 22:48:53
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 22:48:48
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 08:06:11

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Concomitant Medication

Audit	User	Time (GMT)
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:59:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:36
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 14:48:47
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 19:15:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:48:47

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 19:15:03

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin and subcutaneous tissue disorders NEC, HLT: Skin and subcutaneous conditions NEC, PT: Subcutaneous emphysema, LLT: Subcutaneous emphysema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 12:08:49
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 12:08:49
User closed query 'Per DM CLR: Please specify abbreviation GSW. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 11:45:47
Data point term sent to Coder	System	13 Jan 2021 16:46:40
Query 'Per DM CLR: Please specify abbreviation GSW. Update as appropriate.' answered with 'GSW is common medical abbreviation for event but has been updated.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	13 Jan 2021 16:46:29
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	13 Jan 2021 16:46:11
User entered 'SUBCUTANEOUS EMPHYSEMA DUE TO Gunshot wound' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Jan 2021 16:46:11
User opened query 'Per DM CLR: Please specify abbreviation GSW. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 07:48:24
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin and subcutaneous tissue disorders NEC, HLT: Skin and subcutaneous conditions NEC, PT: Subcutaneous emphysema, LLT: Traumatic subcutaneous emphysema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 18:36:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 18:36:50
Data point term sent to Coder	System	11 Dec 2020 17:39:14

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Adverse event

Audit	User	Time (GMT)
User entered 'Subcutaneous Emphysema Due to GSW'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:47
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:28:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:30:34
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:30:36
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered '09 Nov 2020'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:30:40
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
User entered empty.	System	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:30:42
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 14:48:47
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:30:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '15 Nov 2020'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:30:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
User entered empty.	System	11 Dec 2020 17:38:41

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:30:47
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered 'Grade 3/Severe (Grade 3/Severe)'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:30:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'No (N)'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:30:51
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

US3012263

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

US3012263

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
	(b) (4)	
User entered empty.	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Related (NOT RELATED)'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Related (NOT RELATED)'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered 'Not Applicable (NOT APPLICABLE)'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

US3012263
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 14:48:47
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:00:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 15:22:26
DataPoint Un-verified.	Pamela Fidler (b) (4)	16 Apr 2021 15:10:02
Signature has been broken.	Pamela Fidler (b) (4)	16 Apr 2021 15:10:02
User entered '0' reason for change: Data Entry Error	Pamela Fidler (b) (4)	16 Apr 2021 15:10:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 22:48:04
User entered '0'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

US3012263
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 14:48:47
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:00:21
User closed query 'Per source, Other Action Taken, is recorded as, ConMed. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 21:00:19
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 15:22:26
Query 'Per source, Other Action Taken, is recorded as, ConMed. Please verify and update EDC/source accordingly.' answered with 'Updated' (Site from CRA).	Pamela Fidler (b) (4)	16 Apr 2021 15:10:18
Signature has been broken.	Pamela Fidler (b) (4)	16 Apr 2021 15:10:02
User entered '1' reason for change: Data Entry Error	Pamela Fidler (b) (4)	16 Apr 2021 15:10:02
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:37
User opened query 'Per source, Other Action Taken, is recorded as, ConMed. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:31:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:39:48
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:58:35
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Update' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 22:48:09

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Concomitant Medication

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 22:48:04
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 08:08:15
User entered '1'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:25
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered '0'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:28
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:29
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
	(b) (4)	
User entered empty.	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:31:31
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:39:48
User entered empty.	Pamela Fidler (b) (4)	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
User entered '0'	System	11 Dec 2020 17:38:41

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49
User entered '1'	System	11 Dec 2020 17:38:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:48:47

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:21:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:48:47

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:46
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:11

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: GLIBENCLAMIDE;METFORMIN HYDROCHLORIDE, PRODUCTSYNONYM: GLYBURIDE/METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:09:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:09:56
Data point term sent to Coder	System	02 Sep 2020 23:08:34
User entered 'glyburide/metformin'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Diabetes, type II'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '5/500'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'twice daily (BID)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'UN UNK 2008'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 23:08:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 23:08:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:09:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:09:57
Data point term sent to Coder	System	02 Sep 2020 23:09:35
User entered 'lisinopril'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'hypertension'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '20'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'UN UNK 2008'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:10:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:10:58
Data point term sent to Coder	System	02 Sep 2020 23:10:37
User entered 'ibuprofen'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'general myalgias'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '400'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'UN UNK 2005'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
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)	04 Nov 2020 02:25:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 02:25:29
Data point term sent to Coder	System	29 Oct 2020 20:25:04
Data point term sent to Coder	System	29 Oct 2020 20:21:58
Coding entries removed.	Pamela Fidler (b) (4)	29 Oct 2020 20:21:27
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)	02 Sep 2020 23:12:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:12:54
Data point term sent to Coder	System	02 Sep 2020 23:11:40
User entered 'gabapentin'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:22:43
Query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	29 Oct 2020 20:24:22
User entered 'DIABETIC NEUROPATHY L FOOT Sensory' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Oct 2020 20:24:17
User entered 'DIABETIC NEUROPATHY L Foot' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Oct 2020 20:21:27
User opened query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:25:55
Query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:25:25
User opened query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:25:17
User entered 'diabetic neuropathy'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '600'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '22 Jun 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:13:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:13:55
Data point term sent to Coder	System	29 Oct 2020 20:24:01
Data point term sent to Coder	System	29 Oct 2020 20:21:58
Coding entries removed.	Pamela Fidler (b) (4)	29 Oct 2020 20:21:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 09:54:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 09:54:38
Data point term sent to Coder	System	02 Sep 2020 23:11:38
User entered 'ibuprofen'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:22:56
Query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	29 Oct 2020 20:24:03
User entered 'DIABETIC NEUROPATHY L FOOT Sensory' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Oct 2020 20:23:57
User entered 'DIABETIC NEUROPATHY L Foot' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Oct 2020 20:21:49
User opened query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:26:19
User entered 'diabetic neuropathy'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '400'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:48:47
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'UN Feb 2019'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 20:20:51
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 20:20:51
Data point term sent to Coder	System	16 Sep 2020 20:19:34
User entered 'Tylenol'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

FDA-CBER-2022-1614-0013565

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'chills'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '1000' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Oct 2020 18:54:48
User entered '2'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per CDM, per DM CLR re-query: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug as per the DM CLR query below on this page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:23:14
Query 'Per CDM, per DM CLR re-query: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug as per the DM CLR query below on this page. Thank you. ' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	16 Oct 2020 18:54:55
User entered 'mg (mg)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Oct 2020 18:54:48
User opened query 'Per CDM, per DM CLR re-query: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug as per the DM CLR query below on this page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:14:42
User entered 'tablet (TABLET)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'as needed (PRN)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (ORAL)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '07 Sep 2020'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '07 Sep 2020'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of CHILLS did not meet the AE reporting criteria, else add an entry to the AE eCRF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:54:57
Query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of CHILLS did not meet the AE reporting criteria, else add an entry to the AE eCRF. Thank you. ' answered with 'Reported by subject in diary. Additional AE reporting not required' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	16 Oct 2020 18:55:10
User opened query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of CHILLS did not meet the AE reporting criteria, else add an entry to the AE eCRF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:12:24
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of CHILLS did not meet the AE reporting criteria. Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:12:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of CHILLS did not meet the AE reporting criteria. Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Reported on Day 6 of Diary Dose 1' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 14:50:44
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of CHILLS did not meet the AE reporting criteria. Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:19:39
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User entered empty.	System	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User entered empty.	System	16 Sep 2020 20:19:10

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:23:13
User entered empty.	System	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 02:02:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 02:02:42
Data point term sent to Coder	System	16 Sep 2020 20:20:37
User entered 'Amoxicilin'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:15:34
Query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' answered with 'Con-Procedure added' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 14:52:15
User opened query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:21:14
User entered 'Molar extraction'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '875'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'mg (mg)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'twice daily (BID)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 17:32:13
User entered 'other (OTHER)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. twice daily). Kindly update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 08:27:09
Query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. twice daily). Kindly update as appropriate, else clarify.' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	11 Nov 2020 17:32:19
User entered empty; reason for change Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 17:32:13
User opened query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. twice daily). Kindly update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:31:03
User entered 'Every 12 Hours'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (ORAL)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '16 Sep 2020'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	11 Nov 2020 17:32:13
User entered empty.	System	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 17:32:13
User entered empty.	System	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 17:32:13
User entered empty.	System	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 20:22:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 20:22:40
Data point term sent to Coder	System	16 Sep 2020 20:21:44
User entered 'Norco'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:15:45
Query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' answered with 'Con-Procedure added' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 14:52:23
User opened query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:21:32
User entered 'molar extraction'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '10/325'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'mg (mg)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:48:47
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'as needed (PRN)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Oral (ORAL)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '16 Sep 2020'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:12:47
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)	11 Nov 2020 22:47:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:47:38
Data point term sent to Coder	System	11 Nov 2020 22:46:10
User entered 'Robaxin'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:12:51
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:12:53
User entered 'pain, due to gunshot wound (AE #2)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

FDA-CBER-2022-1614-0013622

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:15
User closed query 'Per source, dose is 500mg. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:57:51
Query 'Per source, dose is 500mg. Please review and clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:19
User entered '500' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:12
User opened query 'Per source, dose is 500mg. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:50:19
User entered 'UNK'	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:20
User entered 'mg (mg)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:12
User entered 'Other (OTHER)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:23
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	23 Nov 2020 16:42:12
User entered 'UNK'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per source, frequency is TID. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:02:31
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:28
Query 'Per source, frequency is TID. Please review and clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:21
User entered 'three times daily (TID)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:12
User opened query 'Per source, frequency is TID. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:50:42
User entered 'unknown (UNKNOWN)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:35
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:38
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

FDA-CBER-2022-1614-0013628

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:00
User entered empty.	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:08
User closed query 'Per source, start date was updated to 09Nov20. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:03:06
DataPoint Un-verified.	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:32
User entered '09 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:32
Query 'Per source, start date was updated to 09Nov20. Please review and clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:24
User opened query 'Per source, start date was updated to 09Nov20. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:51:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:04
User entered '08 Nov 2020'	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:11
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per source, end date is 15Nov20. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:03:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:45
Query 'Per source, end date is 15Nov20. Please review and clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	23 Nov 2020 16:42:26
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	23 Nov 2020 16:42:12
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	23 Nov 2020 16:42:12
User opened query 'Per source, end date is 15Nov20. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:51:22
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:38
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:50
User entered '15 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	23 Nov 2020 16:42:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:52
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User entered '3'	System	23 Nov 2020 16:42:12
User entered empty.	System	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User entered '1'	System	23 Nov 2020 16:42:12
User entered empty.	System	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:35
User entered '804 (804)'	System	23 Nov 2020 16:42:12
User entered empty.	System	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:47:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:47:39
Data point term sent to Coder	System	11 Nov 2020 22:46:19
User entered 'Tylenol'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:25
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:24
User entered 'pain, due to gunshot wound (AE #2)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:10
User entered '1000' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	23 Nov 2020 16:42:59
User entered 'UNK'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:12
User entered 'mg (mg)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	23 Nov 2020 16:42:59
User entered 'Other (OTHER)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:15
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	23 Nov 2020 16:42:59
User entered 'UNK'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:17
User entered 'as needed (PRN)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	23 Nov 2020 16:42:59
User entered 'unknown (UNKNOWN)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:19
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:21
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:23
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:26
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	23 Nov 2020 16:42:59
User entered '09 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	23 Nov 2020 16:42:59
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:31
User entered '08 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:28
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:33
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:31
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:32
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:06:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:05
Data point term sent to Coder	System	20 Nov 2020 18:58:26
User entered 'Tramadol'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:06:54
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:06:56
User entered 'Pain, due to gunshot wound (AE #2)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:06:59
User entered '50'	Jennifer Leyva (b) (4)	20 Nov 2020 18:58:20
	(b) (4)	

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:03
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

FDA-CBER-2022-1614-0013660

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:05
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:07:07
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

FDA-CBER-2022-1614-0013662

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:09
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 18:58:20
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:11
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4)	20 Nov 2020 18:58:20
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:14
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:16
User entered '15 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:17
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:35
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Un-verified.	Jessica Ruff (b) (4)	30 Dec 2020 00:39:03
User entered 'No (N)' reason for change: New Information	Jessica Ruff (b) (4)	30 Dec 2020 00:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:20
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:37
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Un-verified.	Jessica Ruff (b) (4)	30 Dec 2020 00:39:03
User entered '15 Dec 2020' reason for change: New Information	Jessica Ruff (b) (4)	30 Dec 2020 00:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:23
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:25
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User entered empty.	System	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User entered empty.	System	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:53
User entered empty.	System	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:02:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:02:00
Data point term sent to Coder	System	20 Nov 2020 19:02:29
User entered 'Alprazolam'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:07:54
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:57
User entered 'Anxiety (AE #4)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:08:17
User entered '2'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:08:19
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:08:21
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:01:45
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:10
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:01:45

FDA-CBER-2022-1614-0013680

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:12
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:17
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:22
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:24
User entered '18 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:26
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Un-verified.	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:39:38
User entered 'No (N)' reason for change: New Information	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:39:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:28
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:21:50
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Un-verified.	Jessica Ruff (b) (4)	30 Dec 2020 00:39:38
User entered '15 Dec 2020' reason for change: New Information	Jessica Ruff (b) (4)	30 Dec 2020 00:39:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:31
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:33
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User entered empty.	System	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User entered empty.	System	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:20:49
User entered empty.	System	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:49
Data point term sent to Coder	System	20 Nov 2020 19:02:30
User entered 'Methocarbamol'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:42
User entered 'No (N)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:02:15

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US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:44
User entered 'pain, due to gunshot wound (AE #2)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:02:15

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:47
User entered '500'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:49
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:51
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:09:53
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:56
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:09:58
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:01
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:02:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:04
User entered '18 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:07
User entered '0'	Jennifer Leyva (b) (4)	20 Nov 2020 19:02:15
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:00
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Un-verified.	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:40:07
User entered 'No (N)' reason for change: New Information	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:40:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Un-verified.	Jessica Ruff (b) (4)	30 Dec 2020 00:40:07
User entered '15 Dec 2020' reason for change: New Information	Jessica Ruff (b) (4)	30 Dec 2020 00:40:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:11
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:02:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:14
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User entered empty.	System	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User entered empty.	System	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:22:17
User entered empty.	System	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: CLOTRIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:38:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:38:43
Data point term sent to Coder	System	03 Feb 2021 19:44:45
Coding entries removed.	Pamela Fidler (b) (4)	03 Feb 2021 19:44:40
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: CLOTRIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:16:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:16:46
Data point term sent to Coder	System	08 Dec 2020 17:59:01
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	08 Dec 2020 17:58:35
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:20
User coded data point as ATC: ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS, ATC: ANTIPROTOZOALS, ATC: AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES, ATC: NITROIMIDAZOLE DERIVATIVES, PRODUCT: CLOTRIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:02:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:02:20
Data point term sent to Coder	System	20 Nov 2020 19:04:32
User entered 'Clotrimazole 1%'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:10:22
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

FDA-CBER-2022-1614-0013712

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per DM CLR: Please update the indication and clarify the type or location of the RASH (e.g. maculopapular, pruritic etc.; bilateral, left, right; arms, legs, face etc.) Review and update indication and ensure to update Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 06:23:31
Query 'Per DM CLR: Please update the indication and clarify the type or location of the RASH (e.g. maculopapular, pruritic etc.; bilateral, left, right; arms, legs, face etc.) Review and update indication and ensure to update Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	03 Feb 2021 19:44:47
DataPoint Un-verified.	Pamela Fidler (b) (4)	03 Feb 2021 19:44:40
User entered 'RASH From laying in hospital Bed (AE #5)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Feb 2021 19:44:40
User opened query 'Per DM CLR: Please update the indication and clarify the type or location of the RASH (e.g. maculopapular, pruritic etc.; bilateral, left, right; arms, legs, face etc.) Review and update indication and ensure to update Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 08:51:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:24
User entered 'Rash (AE #5)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:26
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:48:47
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:29
User entered 'Other (OTHER)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:04:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:31
User entered 'application'	Jennifer Leyva (b) (4)	20 Nov 2020 19:04:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:33
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:36
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:04:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:01:15
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
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)	10 Dec 2020 18:05:08
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	08 Dec 2020 17:58:40
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	08 Dec 2020 17:58:35
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	08 Dec 2020 17:58:35
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)	04 Dec 2020 02:29:08
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:38
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:41
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:04:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:43
User entered '15 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

FDA-CBER-2022-1614-0013721

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:46
User entered '0'	Jennifer Leyva (b) (4)	20 Nov 2020 19:04:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Un-verified.	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:40:56
User entered 'No (N)' reason for change: New Information	Jessica Ruff (b) (4) (b) (4)	30 Dec 2020 00:40:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:48
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:23:23
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Un-verified.	Jessica Ruff (b) (4)	30 Dec 2020 00:40:56
User entered '22 Nov 2020' reason for change: New Information	Jessica Ruff (b) (4)	30 Dec 2020 00:40:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:50
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:04:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:52
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User entered empty.	System	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User entered empty.	System	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:29
User entered empty.	System	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per DM CLR: Con Meds GLIPIZIDE and INSULIN were added on 09 NOV 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:45:33
Query 'Per DM CLR: Con Meds GLIPIZIDE and INSULIN were added on 09 NOV 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen. ' answered with 'Not a worsening. Treatment used while hospitalized.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	08 Dec 2020 17:59:01
User opened query 'Per DM CLR: Con Meds GLIPIZIDE and INSULIN were added on 09 NOV 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 02:30:01
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:24:47
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:34
Data point term sent to Coder	System	20 Nov 2020 19:08:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
User entered 'Glipizide'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:24:48
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:24:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:13
User entered 'DIABETES, TYPE II (while hospitalized)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:24:52
User entered '5'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:24:56
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:24:57
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:08:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:24:59
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:01
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:02
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:04
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:06
User entered '09 Nov 2020'	Jennifer Leyva (b) (4)	20 Nov 2020 19:08:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:07
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:10
User entered '15 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:11
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User entered '1'	System	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User entered '1'	System	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:48
User entered '804 (804)'	System	20 Nov 2020 19:08:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
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, FAST-ACTING, PRODUCT: INSULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 15:12:47
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 Apr 2021 15:12:47
Data point term sent to Coder	System	16 Apr 2021 15:11:52
Coding entries removed.	Pamela Fidler (b) (4)	16 Apr 2021 15:10:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
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- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:20:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:20:51
Data point term sent to Coder	System	08 Dec 2020 18:00:02
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	08 Dec 2020 17:59:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:18
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, FAST-ACTING, PRODUCT: INSULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:43
Data point term sent to Coder	System	20 Nov 2020 19:09:36
User entered 'Insulin'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:20
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:25:21
User entered 'DIABETES, TYPE II (while hospitalized)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per CDM CLR(requery) :the response provided as not appropriate. Kindly update the Dose , if Unknown update to UNK instead of NA.Thanks ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 06:47:35
Query 'Per CDM CLR(requery) :the response provided as not appropriate. Kindly update the Dose , if Unknown update to UNK instead of NA.Thanks ' answered with 'Dose is not Unknown, it is sliding scale as noted below. This is standard method, per PI. Advise of alternate method of entry that is applicable.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	16 Dec 2020 13:32:46
User opened query 'Per CDM CLR(requery) :the response provided as not appropriate. Kindly update the Dose , if Unknown update to UNK instead of NA.Thanks ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:47:07
User closed query '"Per DM CLR: Please review and confirm if the DOSE is unknown and if NA pertains to 'Not Applicable'. If yes, kindly consider updating it to UNK instead. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:47:07
Query '"Per DM CLR: Please review and confirm if the DOSE is unknown and if NA pertains to 'Not Applicable'. If yes, kindly consider updating it to UNK instead. Update eCRF as appropriate. ' answered with 'Not a worsening, treatment used during hospitalization' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	08 Dec 2020 17:59:16
User opened query '"Per DM CLR: Please review and confirm if the DOSE is unknown and if NA pertains to 'Not Applicable'. If yes, kindly consider updating it to UNK instead. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 02:30:57

PRODUCTION RELEASE (v12.003 EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:23
User entered 'NA'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:25:24
User entered 'Other (OTHER)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:26
User entered 'Sliding Scale'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:25:27
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:48:47
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:29
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 22:33:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:00:51
User closed query 'Per source, route of administration is recorded as, Intramuscular. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 21:00:49
Query 'Per source, route of administration is recorded as, Intramuscular. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Pamela Fidler (b) (4)	16 Apr 2021 15:11:11
Signature has been broken.	Pamela Fidler (b) (4)	16 Apr 2021 15:10:54
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Pamela Fidler (b) (4)	16 Apr 2021 15:10:54
User opened query 'Per source, route of administration is recorded as, Intramuscular. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:24:05
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
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)	10 Dec 2020 18:09:05
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate."' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4)	08 Dec 2020 17:59:46
DataPoint Un-verified.	Jennifer Leyva (b) (4)	08 Dec 2020 17:59:42
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	08 Dec 2020 17:59:42
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)	04 Dec 2020 02:31:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:31

PRODUCTION RELEASE (v12.003 EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Route of administration

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:25:32
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:34
User entered '09 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:35
User entered '0'	Jennifer Leyva (b) (4)	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:38
User entered '15 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:39
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User entered '1'	System	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User entered '1'	System	20 Nov 2020 19:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:47

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:31:21
User entered '804 (804)'	System	20 Nov 2020 19:09:04

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:48:47

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:42
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 14:51:21
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:17

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered '16 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 14:52:00

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered 'molar extraction'	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 14:52:00

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:27:29
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'AE #1 = Loose molar. This Con-Proc corresponds to AE #1' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	02 Nov 2020 18:38:23
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 02:04:48
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 14:52:00

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:47

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 14:52:00

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:32
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:06
DataPoint Un-verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:12:23
User entered '09 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:12:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:52
User entered '08 Nov 2020'	Jennifer Leyva (b) (4)	11 Nov 2020 22:46:32

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:32
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:08
DataPoint Un-verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:12:23
	(b) (4)	
User entered 'Bilateral Chest Tube Placement' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:12:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:53
User entered 'Oxygen Treatment'	Jennifer Leyva (b) (4)	11 Nov 2020 22:46:32
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:32
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:13:55
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:32

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:48:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:32
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:13:57
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:32

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:28
User entered '09 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:13:26

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:30
User entered 'CT Scan - Chest'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:13:26

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:33
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:12:31
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:13:26

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:48:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:33
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:13:26

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:36
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:36
User entered '09 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:02

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:36
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:12:38
User entered 'CT Scan - Abdomen and Pelvis'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:02

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:36
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:42
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:30:02

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:48:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:36
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:12:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:02

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:49
User entered '11 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:16

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:51
User entered 'Chest XRAY'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:16

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:52
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:30:16

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:48:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:44
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:54
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:30:16

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:12:57
User entered '12 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:27

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:48:47

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:13:00
User entered 'Chest XRAY'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:27

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:48:47

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:13:02
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:27

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:48:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:13:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:27

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'USA-US006-2020-MRNA-1273-P301000003'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Serious

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Death

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013799

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Laurence'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013802

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Chu'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '3100 Red River Street'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013804

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Austin'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'TX'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '78705'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'US'	System	12 Nov 2020 16:30:08

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 18:32:52
User entered '6'	System	21 Dec 2020 20:13:58
User entered '5'	System	11 Dec 2020 15:43:02
User entered '4'	System	07 Dec 2020 12:58:22
User entered '3'	System	30 Nov 2020 19:34:40
User entered '2'	System	23 Nov 2020 20:11:43
User entered '1'	System	12 Nov 2020 16:30:08

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'USA-US006-2020-MRNA-1273-P301000003'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Serious

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Death

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013815

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Laurence'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Chu'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013819

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '3100 Red River Street'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Austin'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'TX'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013822

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '78705'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'US'	System	12 Nov 2020 16:30:08

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 18:32:52
User entered '6'	System	21 Dec 2020 20:13:58
User entered '5'	System	11 Dec 2020 15:43:02
User entered '4'	System	07 Dec 2020 12:58:22
User entered '3'	System	30 Nov 2020 19:34:40
User entered '2'	System	23 Nov 2020 20:11:43
User entered '1'	System	12 Nov 2020 16:30:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered '12/Nov/2020 11:30'	System	12 Nov 2020 16:30:08

FDA-CBER-2022-1614-0013826

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:48:47

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.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 16:30:08

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'USA-US006-2020-MRNA-1273-P301000003'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Serious

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Death

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013831

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013835

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Laurence'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Chu'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '3100 Red River Street'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013838

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Austin'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013839

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'TX'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '78705'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'US'	System	12 Nov 2020 16:30:08

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 18:32:52
User entered '6'	System	21 Dec 2020 20:13:58
User entered '5'	System	11 Dec 2020 15:43:02
User entered '4'	System	07 Dec 2020 12:58:22
User entered '3'	System	30 Nov 2020 19:34:40
User entered '2'	System	23 Nov 2020 20:11:43
User entered '1'	System	12 Nov 2020 16:30:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:51:05
User entered '23/Nov/2020 20:11'	System	23 Nov 2020 20:11:43

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:48:47

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.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:34:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:51:05
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 20:11:43

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'USA-US006-2020-MRNA-1273-P301000003'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Serious

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Death

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013852

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013853

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Laurence'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Chu'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '3100 Red River Street'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Austin'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'TX'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '78705'	System	12 Nov 2020 16:28:37

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'US'	System	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 18:32:52
User entered '6'	System	21 Dec 2020 20:13:58
User entered '5'	System	11 Dec 2020 15:43:02
User entered '4'	System	07 Dec 2020 12:58:22
User entered '3'	System	30 Nov 2020 19:34:40
User entered '2'	System	23 Nov 2020 20:11:43
User entered '1'	System	12 Nov 2020 16:30:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 16:12:13
User entered '30/Nov/2020 19:34'	System	30 Nov 2020 19:34:40

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:48:47

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.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:13
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 12:58:13
User entered '1'	(b) (4), (b) (6)	30 Nov 2020 19:34:40

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'USA-US006-2020-MRNA-1273-P301000003'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Serious

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Death

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Laurence'	System	12 Nov 2020 16:28:37

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Chu'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '3100 Red River Street'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Austin'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'TX'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '78705'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'US'	System	12 Nov 2020 16:30:08

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 18:32:52
User entered '6'	System	21 Dec 2020 20:13:58
User entered '5'	System	11 Dec 2020 15:43:02
User entered '4'	System	07 Dec 2020 12:58:22
User entered '3'	System	30 Nov 2020 19:34:40
User entered '2'	System	23 Nov 2020 20:11:43
User entered '1'	System	12 Nov 2020 16:30:08

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 14:48:47
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:13
User entered '07/Dec/2020 07:58'	System	07 Dec 2020 12:58:22

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:48:47

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.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:13:40
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 16:12:13
User entered '1'	(b) (4), (b) (6)	07 Dec 2020 12:58:22

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'USA-US006-2020-MRNA-1273-P301000003'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Serious

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

Death

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Laurence'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013890

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Chu'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '3100 Red River Street'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013892

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Austin'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'TX'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013894

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '78705'	System	12 Nov 2020 16:28:37

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'US'	System	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 18:32:52
User entered '6'	System	21 Dec 2020 20:13:58
User entered '5'	System	11 Dec 2020 15:43:02
User entered '4'	System	07 Dec 2020 12:58:22
User entered '3'	System	30 Nov 2020 19:34:40
User entered '2'	System	23 Nov 2020 20:11:43
User entered '1'	System	12 Nov 2020 16:30:08

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 14:48:47
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:10:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '11/Dec/2020 09:43'	(b) (4) System	11 Dec 2020 15:43:02

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:48:47

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)	13 Apr 2021 21:10:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 20:13:40
User entered '1'	(b) (4), (b) (6)	11 Dec 2020 15:43:02

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'USA-US006-2020-MRNA-1273-P301000003'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Serious

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Death

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Laurence'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Chu'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '3100 Red River Street'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Austin'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013911

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'TX'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '78705'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'US'	System	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 18:32:52
User entered '6'	System	21 Dec 2020 20:13:58
User entered '5'	System	11 Dec 2020 15:43:02
User entered '4'	System	07 Dec 2020 12:58:22
User entered '3'	System	30 Nov 2020 19:34:40
User entered '2'	System	23 Nov 2020 20:11:43
User entered '1'	System	12 Nov 2020 16:30:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:10:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
User entered '21/Dec/2020 15:13'	(b) (4) System	21 Dec 2020 20:13:58

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:48:47

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)	13 Apr 2021 21:10:02
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 20:14:03
User entered '1'	(b) (4), (b) (6)	21 Dec 2020 20:13:58

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'USA-US006-2020-MRNA-1273-P301000003'	System	12 Nov 2020 16:28:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Death

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013923

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:47

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Laurence'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013926

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Chu'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013927

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '3100 Red River Street'	System	12 Nov 2020 16:28:37

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Austin'	System	12 Nov 2020 16:28:37

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'TX'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013930

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '78705'	System	12 Nov 2020 16:28:37

FDA-CBER-2022-1614-0013931

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 01:03:07
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'US'	System	12 Nov 2020 16:30:08

US3012263
Folder: SAE USA-US006-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:48:47
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 18:32:52
User entered '6'	System	21 Dec 2020 20:13:58
User entered '5'	System	11 Dec 2020 15:43:02
User entered '4'	System	07 Dec 2020 12:58:22
User entered '3'	System	30 Nov 2020 19:34:40
User entered '2'	System	23 Nov 2020 20:11:43
User entered '1'	System	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:48:47

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	19 Apr 2021 22:04:01
User entered '19/Apr/2021 11:32'	System	19 Apr 2021 18:32:52

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:48:47

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.	Laurence Chu (b) (4)	19 Apr 2021 22:04:01
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:32:52