US3202179 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:46:52

All time stamps listed in this document are displayed in GMT

Participant ID   US3202179

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0445968

US3202179

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **13 Feb 2021 02:10:02**

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: Screening

Form: Demographics

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
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

US3202179

Folder: Screening

Form: Enrollment

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Date of Informed Consent *(dd MMM yyyy)*	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020

Protocol Version
- Amendment 1 ◯
- Amendment 2 ⬤
- Amendment 3 ◯
- Amendment 4 ◯
- Amendment 5 ◯

Was participant enrolled in the study?
- Yes ⬤
- No ◯

If No, indicate reason for screen fail
- Withdrew Consent ◯
- Inclusion/Exclusion ◯
- Cohort Full ◯
- Other ◯

If reason for screen fail is Other, specify _____

Was this participant screened previously?
- Yes ◯
- No ⬤

If Yes, previous participant number _____

Enrollment Trigger	1

US3202179

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Did the participant meet all eligibility criteria?   Yes ●

                                                             No ○

Were any significant conditions reported?   Yes ⬤

                                                                                No ◯

US3202179

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: Screening

Form: Medical History (2)

Data signed: ▢ (b) (4) ▢ **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Condition	COPD
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Condition	ANGINA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3202179

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Condition	HYPERTENSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3202179

Folder: Screening

Form: Medical History (5)

Data signed: ▨ (b) (4) ▨ **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3202179

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Condition	CHRONIC KIDNEY DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3202179

Folder: Screening

Form: Medical History (7)

Data signed: ▓ (b) (4) ▓ **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Condition	ATRIAL FIB
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3202179

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Condition	CORONARY ARTERY DISEASE (3 STENTS)
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	14 AUG 2020
Time of assessment *(00:00-23:59)*	09:41 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 09:41
Height *(xxx.x)*	178.0 cm
Weight *(xxx.x)*	101.0 kg
BMI *(xxx.x)*	31.87729 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)	

FDA-CBER-2022-1614-0445982

US3202179

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **13 Feb 2021 02:10:02**

Generated On: 09 Jun 2021 15:46:52

Was the physical examination performed?	Yes ⬤
	No ◯

Date of examination *(dd MMM yyyy)*	14 AUG 2020

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

US3202179

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **13 Feb 2021 02:10:02**

Generated On: 09 Jun 2021 15:46:52

Occupational Risk

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

Specify _____

Location and Living Circumstances Risk (check all that apply)

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

Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **13 Feb 2021 02:10:02**
Generated On: 09 Jun 2021 15:46:52

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	

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

Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | VISIT1 |

FDA-CBER-2022-1614-0445986

What was the date of randomization? *(dd MMM yyyy)*	14 AUG 2020
What was the participant's randomization number?	186323

In what Cohort was the participant enrolled?

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

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

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

FDA-CBER-2022-1614-0445987

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **13 Feb 2021 02:10:02**
Generated On: 09 Jun 2021 15:46:52

Height	ND - Not Done
Weight	ND - Not Done

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **13 Feb 2021 02:10:02**

Generated On: 09 Jun 2021 15:46:52

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)*	14 AUG 2020
Time of assessment *(00:00-23:59)*	09:41 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 09:41
Temperature *(xxx.x)*	35.7 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	21 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	89 mmHg
Diastolic Blood Pressure units	MMHG

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **13 Feb 2021 02:10:02**

Generated On: 09 Jun 2021 15:46:52

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)*	14 AUG 2020
Time of assessment *(00:00-23:59)*	11:01 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:01
Temperature *(xxx.x)*	35.9 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	94 mmHg
Diastolic Blood Pressure units	MMHG

US3202179

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: ▓▓ (b) (4) ▓▓ **13 Feb 2021 02:10:02**

Generated On: 09 Jun 2021 15:46:52

Was the physical examination performed?   Yes ●

                                                    No ○

Date of examination *(dd MMM yyyy)*   14 AUG 2020

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

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)*	14 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:28 (24 HR)
Treatment Date and Time (derived)	14 AUG 2020 10:28
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

Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Feb 2021 02:10:02**
Generated On: 09 Jun 2021 15:46:52

Was the sample collected?	Yes	⬤
	No	◯

Collection date *(dd MMM yyyy)*	14 AUG 2020
Collection time *(00:00-23:59)*	09:52 (24 HR)
Collection date and time (derived)	14 AUG 2020 09:52

US3202179

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **13 Feb 2021 02:10:02**

Generated On: 09 Jun 2021 15:46:52

Collection date *(dd MMM yyyy)*			14 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:49	14 AUG 2020 09:49
Nasopharyngeal Swab 2	No		

US3202179
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:10:02**
Generated On: 09 Jun 2021 15:46:52

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**	
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	14 AUG 2020 10:48
PC Close Date & Time	14 AUG 2020 13:18

FDA-CBER-2022-1614-0445996

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 1, AFTER VACCINATION
	(AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ◯
	No ◯
Please record your **TEMPERATURE in °F**	_____
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ◯
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	_____
To **PREVENT** pain or fever from occurring	_____
PC Time Stamp	_____
PC Open Date & Time	14 AUG 2020 14:13
PC Close Date & Time	15 AUG 2020 11:59

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:46:52

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**	

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	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:46:52

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**	_____
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	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-0445999

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 4

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.0 °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	17 AUG 2020 17:12
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 5

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.1 °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	18 AUG 2020 15:04
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.0 °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	19 AUG 2020 18:38
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

| **TIMEPOINT** | **DAY 7** |

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	20 AUG 2020 18:05
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

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 ◯
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	14 AUG 2020 10:48
PC Close Date & Time	14 AUG 2020 13:18

FDA-CBER-2022-1614-0446004

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ◯
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ◯
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ◯
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ◯
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	
PC Open Date & Time	14 AUG 2020 14:13
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-0446005

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:52

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 ◯
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	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 3

Please record - **PAIN AT INJECTION SITE.**	None ◯
Please select one response below	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.**	None ◯
Please select one response below	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	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 4

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

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

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

Yes ◯
No ◯

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

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

_____

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

Yes ◯
No ◯

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

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

_____

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

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

PC Time Stamp	_____
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 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	19 AUG 2020 09:34
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

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	19 AUG 2020 18:38
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:52

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	20 AUG 2020 18:06
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

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

FDA-CBER-2022-1614-0446012

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⚪ Yes ⚪
PC Time stamp	
PC Open Date & Time	14 AUG 2020 10:48
PC Close Date & Time	14 AUG 2020 13:18

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

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	
PC Open Date & Time	14 AUG 2020 14:13
PC Close Date & Time	15 AUG 2020 11:59

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52

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	
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

TIMEPOINT	DAY 3

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

FATIGUE
- None ⬭
- No interference with activity ⬭
- Some interference with activity ⬭
- Significant; prevents daily activity ⬭

MUSCLE ACHES ALL OVER BODY
- None ⬭
- No interference with activity ⬭
- Some interference with activity ⬭
- Significant; prevents daily activity ⬭

JOINT ACHES IN SEVERAL JOINTS
- None ⬭
- No interference with activity ⬭
- Some interference with activity ⬭
- Significant; prevents daily activity ⬭

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

CHILLS
- None ⬭
- No interference with activity ⬭
- Some interference with activity not requiring medical attention ⬭
- Prevents daily activity and requires medical attention ⬭

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

FDA-CBER-2022-1614-0446018

	Yes ◯
PC Time stamp	
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:52

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	
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

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	18 AUG 2020 15:06
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52

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 ●

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52

	Yes ◯
PC Time stamp	19 AUG 2020 18:39
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52

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	20 AUG 2020 18:06
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3202179

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: ▨ (b) (4) ▨ **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3202179

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3202179

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?	Yes ⬤
	No ⭕
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 AUG 2020
Please select one status for the follow-up contact	Contact Made ⭕
	Contact Not Made ⬤
Comments	NO ANSWER

If Contact Not Made, please provide Comments

US3202179

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: ▓ (b) (4) ▓ **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ⬤

     No ◯

Continuing Flag   1

US3202179

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	4 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3202179

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ●

                                                                      No ○

Continuing Flag   1

US3202179

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **13 Feb 2021 02:10:02**

Generated On: 09 Jun 2021 15:46:52

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT2

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **13 Feb 2021 02:10:02**

Generated On: 09 Jun 2021 15:46:52

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	24 SEP 2020
Time of assessment *(00:00-23:59)*	08:57 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 08:57
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

Timepoint	Pre-Dose ◯
	Post-Dose ⬤

Were vital signs assessed?	Yes ⬤
	No ◯

Date of assessment *(dd MMM yyyy)*	24 SEP 2020
Time of assessment *(00:00-23:59)*	10:14 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:14
Temperature *(xxx.x)*	36.5 C

Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯

If Other, specify	
Pulse *(xxx)*	44 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

US3202179

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **13 Feb 2021 02:10:02**

Generated On: 09 Jun 2021 15:46:52

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)*	24 SEP 2020
What was the treatment time? *(00:00-23:59)*	09:38 (24 HR)
Treatment Date and Time (derived)	24 SEP 2020 09:38
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

Was the sample collected?	Yes	⬤
	No	◯

Collection date *(dd MMM yyyy)*	24 SEP 2020
Collection time *(00:00-23:59)*	09:04 (24 HR)
Collection date and time (derived)	24 SEP 2020 09:04

FDA-CBER-2022-1614-0446039

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **13 Feb 2021 02:10:02**
Generated On: 09 Jun 2021 15:46:52

Collection date *(dd MMM yyyy)*   24 SEP 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:01	24 SEP 2020 09:01
Nasopharyngeal Swab 2	No		

US3202179

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 02:10:02**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag   1

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

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**	
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	24 SEP 2020 09:58
PC Close Date & Time	24 SEP 2020 12:28

TIMEPOINT	DAY 1, AFTER VACCINATION
	(AT HOME)

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

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

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

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

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

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

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

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

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	24 SEP 2020 13:23
PC Close Date & Time	25 SEP 2020 11:59

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:46:52

TIMEPOINT   DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	25 SEP 2020 16:33
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-0446044

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:52

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	26 SEP 2020 16:43
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-0446045

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	27 SEP 2020 17:55
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:46:52

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	29 SEP 2020 09:34
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	29 SEP 2020 16:19
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:52

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**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	30 SEP 2020 18:01
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

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 ◯

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	24 SEP 2020 09:58
PC Close Date & Time	24 SEP 2020 12:28

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ◯ Does not interfere with activity ◯ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯ Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯ No ◯
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯ No ◯
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ◯ Does not interfere with activity ◯ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯ Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	
PC Open Date & Time	24 SEP 2020 13:23
PC Close Date & Time	25 SEP 2020 11:59

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:46:52

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	25 SEP 2020 16:33
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:46:52

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	26 SEP 2020 16:43
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 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	27 SEP 2020 17:55
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 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	29 SEP 2020 09:34
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

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	29 SEP 2020 16:20
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

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	30 SEP 2020 18:03
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

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	
PC Open Date & Time	24 SEP 2020 09:58
PC Close Date & Time	24 SEP 2020 12:28

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

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	◯

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

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

PC Time stamp	
PC Open Date & Time	24 SEP 2020 13:23
PC Close Date & Time	25 SEP 2020 11:59

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	25 SEP 2020 16:34
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52

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	26 SEP 2020 16:44
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

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	27 SEP 2020 17:56
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

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	29 SEP 2020 09:35
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52

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	29 SEP 2020 16:20
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52

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	30 SEP 2020 18:02
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3202179

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 1 OCT 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3202179

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3202179

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 8 OCT 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3202179

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3202179

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?	Yes ●
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3202179

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 02:09:59**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3202179

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **13 Feb 2021 02:10:03**

Generated On: 09 Jun 2021 15:46:52

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT3

US3202179

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **13 Feb 2021 02:10:03**

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	23 OCT 2020
Time of assessment *(00:00-23:59)*	08:41 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 08:41
Temperature *(xxx.x)*	36.4 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202179
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 02:10:03**
Generated On: 09 Jun 2021 15:46:52

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.

Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: ████ (b) (4) ████ **13 Feb 2021 02:10:03**
Generated On: 09 Jun 2021 15:46:52

Was the sample collected?	Yes ⬤
	No ◯

Collection date *(dd MMM yyyy)*	23 OCT 2020
Collection time *(00:00-23:59)*	08:51 (24 HR)
Collection date and time (derived)	23 OCT 2020 08:51

US3202179
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 02:10:03**
Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯ |

FDA-CBER-2022-1614-0446085

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 OCT 2020 17:07:10
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 15:56:06
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 15:23:31
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 14:33:49
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	25 NOV 2020 14:13:27
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	29 NOV 2020 12:33:48
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	06 DEC 2020 17:14:00
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	13 DEC 2020 12:52:53
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	20 DEC 2020 17:49:35
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	27 DEC 2020 14:07:27
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	03 JAN 2021 16:20:51
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 11:58:04
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	20 JAN 2021 11:50:21
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	24 JAN 2021 18:29:03
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	31 JAN 2021 14:52:59
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	09 FEB 2021 18:24:54
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	14 FEB 2021 14:51:19
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	21 FEB 2021 14:12:08
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	28 FEB 2021 17:57:48
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	07 MAR 2021 14:29:40
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	14 MAR 2021 14:54:02
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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-2022-1614-0446108

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ⚪
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	28 MAR 2021 15:47:10
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	04 APR 2021 13:13:02
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	11 APR 2021 15:49:59
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 APR 2021 17:09:56
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 APR 2021 12:41:59
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 14:17:44
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	**DAY 271**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT   **DAY 278**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

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

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-2022-1614-0446118

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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-2022-1614-0446120

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 $\geq$ 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 ⭕

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	**DAY 299**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature $\geq$ 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-2022-1614-0446124

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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-2022-1614-0446128

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 $\geq$ 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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 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-2022-1614-0446132

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	**DAY 341**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0446136

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

FDA-CBER-2022-1614-0446138

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	**DAY 362**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	**DAY 369**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	**DAY 390**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0446150

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⟳ Yes ⟳
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⟳ Yes ⟳
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⟳
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⟳ Yes ⟳

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

Fever (Temperature ≥ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⟳
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⟳ Yes ⟳

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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-2022-1614-0446164

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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):

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 ⬭

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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):

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 ○

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT   DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 $\geq$ 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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ⃝

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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):

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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):

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 $\geq$ 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 ○

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 $\geq$ 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-2022-1614-0446186

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ⭕

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

FDA-CBER-2022-1614-0446194

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT   DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT   DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 $\geq$ 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 ⬭

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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):

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 ◯

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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-2022-1614-0446206

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT DAY 600

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 $\geq$ 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-2022-1614-0446212

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	**DAY 614**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT DAY 621

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT   **DAY 628**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 $\geq$ 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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 MAY 2022 00:01
Patient Cloud Close Date & Time	12 MAY 2022 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2022 00:01
Patient Cloud Close Date & Time	19 MAY 2022 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 $\geq$ 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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ⬭

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	**DAY 670**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 $\geq$ 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-2022-1614-0446232

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 JUN 2022 00:01
Patient Cloud Close Date & Time	23 JUN 2022 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ⚪

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

FDA-CBER-2022-1614-0446244

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	31 JUL 2022 00:01
Patient Cloud Close Date & Time	04 AUG 2022 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT　　　　　　　　　　　　　　　　　　　DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 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-2022-1614-0446246

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 AUG 2022 00:01
Patient Cloud Close Date & Time	11 AUG 2022 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	**DAY 733**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

FDA-CBER-2022-1614-0446248

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ◯

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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-2022-1614-0446252

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 $\geq$ 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 ⭘

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 SEP 2022 00:01
Patient Cloud Close Date & Time	08 SEP 2022 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ○

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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):

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 ⭕

FDA-CBER-2022-1614-0446260

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	**DAY 782**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ○

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

Fever (Temperature $\geq$ 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 ○

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 OCT 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT	**DAY 789**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

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

Fever (Temperature $\geq$ 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-2022-1614-0446264

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 ⃝

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:46:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 17:57:28

US3202179

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 12:44:16**

Generated On: 09 Jun 2021 15:46:52

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 13 NOV 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3202179

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: ▓▓ (b) (4) ▓▓ **26 Mar 2021 12:44:16**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ●

                                                                     No ○

Continuing Flag   1

US3202179

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 DEC 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3202179

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3202179
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **09 Apr 2021 15:25:27**
Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 JAN 2021
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●
Comments	LEFT A VOICE MESSAGE

If Contact Not Made, please provide Comments

US3202179

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3202179

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 FEB 2021
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●
Comments	LEFT A VOICE MESSAGE.
	SUBJECT CALLED BACK ON
If Contact Not Made, please provide Comments	19FEB. 2021

US3202179

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Yes ●

No ○

Continuing Flag 1

US3202179

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) **09 Apr 2021 15:25:53**

Generated On: 09 Jun 2021 15:46:52

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT4

US3202179

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **09 Apr 2021 15:25:53**

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	30 MAR 2021
Time of assessment *(00:00-23:59)*	13:00 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 13:00
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202179

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **09 Apr 2021 15:25:53**

Generated On: 09 Jun 2021 15:46:52

Was the physical examination performed?	Yes ●
	No ◯

Date of examination *(dd MMM yyyy)*	30 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)*	30 MAR 2021
Collection time *(00:00-23:59)*	13:05 (24 HR)
Collection date and time (derived)	30 MAR 2021 13:05

US3202179

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 15:25:53**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ●

                                                                No ◯

Continuing Flag   1

US3202179
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

| 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 _____

US3202179

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ◯

No ◯

Continuing Flag

US3202179
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:46:52

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 $\bigcirc$
	No $\bigcirc$

US3202179

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

Form: Visit Date

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	1 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	UNBLND_DECIDE

US3202179

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 17:57:02

Generated On: 09 Jun 2021 15:46:52

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

US3202179

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

Form: Vital Signs - Dosing

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Height	
Weight	
BMI (xxx.x)	

Height	
Weight	
BMI *(xxx.x)*	
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	1 FEB 2021
Time of assessment *(00:00-23:59)*	13:03 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 13:03
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	94 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	94 mmHg
Diastolic Blood Pressure units	MMHG

US3202179

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose ⬭
	Post-Dose ⬛
Were vital signs assessed?	Yes ⬛
	No ⬭
Date of assessment (dd MMM yyyy)	1 FEB 2021
Time of assessment (00:00-23:59)	14:16 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 14:16
Temperature (xxx.x)	36.5 C
Route of measurement	Oral ⬛
	Axillary ⬭
	Other ⬭
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

US3202179

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

Form: Physical Examination

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

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? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	1 FEB 2021
What was the treatment time? *(00:00-23:59)*	13:26 (24 HR)
Treatment Date and Time (derived)	1 FEB 2021 13:26
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

US3202179

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	1 FEB 2021
Collection time *(00:00-23:59)*	13:23 (24 HR)
Collection date and time (derived)	1 FEB 2021 13:23

US3202179

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?	Yes ●
	No ◯
Collection date *(dd MMM yyyy)*	1 FEB 2021
Collection time *(00:00 - 23:59)*	13:17
Collection Date and Time (derived)	1 FEB 2021 13:17

US3202179

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

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit? 　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Continuing Flag 　　　　　　　　　　　　　　　　　　　　1

US3202179

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **09 Apr 2021 15:25:53**

Generated On: 09 Jun 2021 15:46:52

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

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

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

Comments

If Contact Not Made, please provide Comments

US3202179

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 15:25:53**

Generated On: 09 Jun 2021 15:46:52

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

Continuing Flag	1
OLD29 Placebo Flag	1

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

Visit date (dd MMM yyyy)	1 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | OLD29 |

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	1 MAR 2021
Time of assessment *(00:00-23:59)*	13:56 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 13:56
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	92 mmHg
Diastolic Blood Pressure units	MMHG

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Timepoint	Pre-Dose ⊖
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⊖
Date of assessment *(dd MMM yyyy)*	1 MAR 2021
Time of assessment *(00:00-23:59)*	14:36 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 14:36
Temperature *(xxx.x)*	36.4 C
Route of measurement	Oral ⬤
	Axillary ⊖
	Other ⊖
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	99 mmHg
Diastolic Blood Pressure units	MMHG

US3202179

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

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.

US3202179

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

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)*	1 MAR 2021
What was the treatment time? *(00:00-23:59)*	14:03 (24 HR)
Treatment Date and Time (derived)	1 MAR 2021 14:03
Which arm was used to give treatment?	Left Arm ●
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3202179

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3202179

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

| 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

US3202179

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3202179
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **09 Apr 2021 15:25:27**
Generated On: 09 Jun 2021 15:46:52

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

Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | OLD57 |

US3202179

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	30 MAR 2021
Time of assessment *(00:00-23:59)*	13:00 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 13:00
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202179

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:25:27

Generated On: 09 Jun 2021 15:46:52

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   30 MAR 2021

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

US3202179

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

| Was the sample collected? | Yes ⬤ |
| | No ◯ |

Collection date *(dd MMM yyyy)*	30 MAR 2021
Collection time *(00:00-23:59)*	13:05 (24 HR)
Collection date and time (derived)	30 MAR 2021 13:05

US3202179

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **19 Mar 2021 13:08:48**

Generated On: 09 Jun 2021 15:46:52

Did the participant experience any adverse events?   Yes ●

No ○

If Yes, enter details on the Adverse Events form.

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

AEID	USA-US128-2021-MRNA-1273-P30 1000013
Adverse event	WORSENING OF CORONARY ARTERY DISEASE

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

Was this a Solicited Adverse Reaction?　Yes ○ / No ●

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

Start date *(dd MMM yyyy)*　19 MAR 2021

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

AE start date and time (derived)

Ongoing?　Yes ○ / No ●

　If not Ongoing, end date *(dd MMM yyyy)*　22 MAR 2021

　End time *(00:00-23:59)*

AE End Date and Time (derived)

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

Is the adverse event serious?　Yes ● / No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	19 MAR 2021
Hospital Discharge Date *(dd MMM yyyy)*	24 MAR 2021

　Admitted to ICU?　Yes ○ / No ● / Unknown ○

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

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

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

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

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

Narrative

SUBJECT FOUND TO HAVE CAD UPON CARDIAC WORKUP FOR APPENDECTOMY AND WAS ADMITTED FOR CARDIAC CATHETERIZATION AND STENTING. POOR HISTORIAN--NUMBER OF STENTS OR OTHER DETAILS NOT YET KNOWN BUT MED RECORDS REQUESTED. SUBJECT UNDERWENT CARDIAC CATHETERIZATION AND WAS FOUND TO HAVE 90% STENOSIS IN LAD, STENT PLACED, RECORDS REDACTED AND EMAILED TO SAFETY UPDATED INFORMATION: SUBJECT'S MEDICAL RECORDS AND CALLS WITH SUBJECT CLARIFYING RECORDS REVEALED THAT SUBJECT HAD A HISTORY OF CAD UPON ENTERING THE STUDY AND HAD 3 CARDIAC STENTS IN 2019. THIS AE TERM WAS UPDATED TO "WORSENING" AND CAD WAS ADDED TO MEDICAL HISTORY

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

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:57:02

Generated On: 09 Jun 2021 15:46:52

AEID	
Adverse event	APPENDICITIS
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	19 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:57:02

Generated On: 09 Jun 2021 15:46:52

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

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

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

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

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

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

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

Narrative — SUBJECT PLANNING TO HAVE APPENDECTOMY IN APRIL 2021 BUT WAS UNABLE TO UNDERGO THAT PROCEDURE DUE TO FAILED CARDIAC WORKUP PRIOR TO APPENDECTOMY

Serious Adverse Event Derived (CSA Programming Field Ony) — 0

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

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

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

AEID	USA-US128-2021-MRNA-1273-P30 1000013
Adverse event	WIDE COMPLEX VENTRICULAR TACHYCARDIA

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)*	20 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	21 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

Is the adverse event serious? Yes ● No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	19 MAR 2021
Hospital Discharge Date *(dd MMM yyyy)*	24 MAR 2021

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

SUBJECT HAS HISTORY OF CHRONIC AFIB AND WAS SEEN BY CARDIOLOGY ON 20/MAR/21 FOR CARDIAC CLEARANCE FOR APPENDECTOMY SURGERY. THE CARDIOLOGIST NOTED THAT HE WAS HAVING WIDE COMPLEX TACHYCARDIA EPISODES SO AN ISCHEMIC WORKUP WAS PLANNED WITH NUCLEAR STRESS TEST PRIOR TO APPROVAL OF APPENDECTOMY. HOWEVER, THE STESS TEST WAS CANCELLED DUE TO TO RECURRENCE OF ARRHYTHMIAS AND SUBJECT WAS SENT TO MAIN HOSPITAL FOR CARDIAC CATHETERIZATION AND FURTHER EVAL.

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

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 17:57:02

Generated On: 09 Jun 2021 15:46:52

AEID	
Adverse event	L4 VERTEBRAL COMPRESSION FX

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

Was this a Solicited Adverse Reaction?   Yes ○   No ●

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

Start date *(dd MMM yyyy)*	19 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ●   No ○

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

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

Is the adverse event serious?   Yes ○   No ●

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

Admitted to ICU?   Yes ○   No ○   Unknown ○

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

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	INCIDENTAL FINDING. SUBJ ADMITTED FOR APPENDICITIS, HAD CARDIAC W/U W STENT. FX FOUND ON X-RAY
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

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

AEID	USA-US128-2021-MRNA-1273-P30 1000013
Adverse event	ACUTE CORONARY SYNDROME >24 HRS DURATION

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

Was this a Solicited Adverse Reaction?　　Yes ○　No ●

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

Start date *(dd MMM yyyy)*	19 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?　　Yes ○　No ●

If not Ongoing, end date *(dd MMM yyyy)*	22 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

Is the adverse event serious?　　Yes ●　No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	19 MAR 2021
Hospital Discharge Date *(dd MMM yyyy)*	24 MAR 2021

Admitted to ICU?　　Yes ○　No ●　Unknown ○

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 17:57:02

Generated On: 09 Jun 2021 15:46:52

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

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

Outcome

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

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

Narrative

	IN MEDICAL RECORDS RELATED TO WORSENING OF CAD AND STENT PLACEMENT, SUBJECT IS NOTED AS HAVING ACUTE CORONARY SYNDROME OF >24 HOURS DURATION BUT NO HISTORY OF CARDIAC ARREST OR MI
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

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

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

                                                                             No ○

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

Name of Medication | TYLENOL

Prophylaxis

Yes ◯

No ⬤

Indication | MIGRAINES

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)*	UN UNK 2000
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 (2)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Name of Medication	ELIQUIS
Prophylaxis	Yes ⭘
	No ⬤
Indication	ATRIAL FIBRILLATION
Dose per administration	5
Dose unit	mg ⬤
	ug ⭘
	mL ⭘
	g ⭘
	IU ⭘
	tablet ⭘
	capsule ⭘
	puff ⭘
	Other ⭘
If dose unit is Other, specify	
Frequency	once daily ⭘
	twice daily ⬤
	three times daily ⭘
	four times daily ⭘
	every other day ⭘
	every week ⭘
	every month ⭘
	as needed ⭘
	once ⭘
	unknown ⭘
	other ⭘
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ⭘
	Subcutaneous ⭘
	Transdermal ⭘
	Intraocular ⭘

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)*	UN 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 ●

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	9 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	9 OCT 2020
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

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

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)*	22 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	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 (6)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Name of Medication	PLAVIX
Prophylaxis	Yes ○
	No ●
Indication	CAD STENT PLACEMENT
Dose per administration	75
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 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	METOPROLOL

Prophylaxis	Yes ◯
	No ⬤

Indication	CAD
	ARRHYTHMIAS- AT FIB
	WIDE-COMPLEX VENTRICULAR
	TACHYCARDIA

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)*	24 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	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) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ⭘
	No ⬤
Indication	CAD
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 ⭘

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)*	22 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Name of Medication	MIDOLAZAM

Prophylaxis	Yes ⭕
	No 🔘

Indication	PROCEDURE SEDATION FOR CAD STENT

Dose per administration	0.5

Dose unit	mg 🔘
	ug ⭕
	mL ⭕
	g ⭕
	IU ⭕
	tablet ⭕
	capsule ⭕
	puff ⭕
	Other ⭕

If dose unit is Other, specify

Frequency	once daily ⭕
	twice daily ⭕
	three times daily ⭕
	four times daily ⭕
	every other day ⭕
	every week ⭕
	every month ⭕
	as needed ⭕
	once 🔘
	unknown ⭕
	other ⭕

If frequency is Other, specify

Route of administration	Oral ⭕
	Topical ⭕
	Subcutaneous ⭕
	Transdermal ⭕

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	22 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*   22 MAR 2021

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

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

Name of Medication	FENTANYL

Prophylaxis	Yes ◯
	No ⬤

Indication	PROCEDURE SEDATION FOR CAD STENT

Dose per administration	25

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral ◯
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯

	Intraocular ◯
	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ⬤
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	22 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	22 MAR 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	DIPHENHYDRAMINE

Prophylaxis	Yes ●
	No ○

Indication	PROPHYLAXIS
Dose per administration	25

Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify	

Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ●
	unknown ○
	other ○

If frequency is Other, specify	

Route of administration	Oral ○
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	22 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	22 MAR 2021
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Name of Medication	FUROSEMIDE

Prophylaxis	
Yes	○
No	●

Indication	CHF
Dose per administration	40

Dose unit	
mg	●
ug	○
mL	○
g	○
IU	○
tablet	○
capsule	○
puff	○
Other	○

If dose unit is Other, specify

Frequency	
once daily	●
twice daily	○
three times daily	○
four times daily	○
every other day	○
every week	○
every month	○
as needed	○
once	○
unknown	○
other	○

If frequency is Other, specify

Route of administration	
Oral	●
Topical	○
Subcutaneous	○
Transdermal	○
Intraocular	○

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)*	24 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	GABAPENTIN

Prophylaxis	Yes ◯
	No ⬤

Indication	L4 VERTEBRAL COMPRESSION FX

Dose per administration	300

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 ◯

FDA-CBER-2022-1614-0446348

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)*	24 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	3
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 (14)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ⬤
	No ◯
Indication	SUPPLEMENT
Dose per administration	1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration	
Oral	⬤
Topical	◯
Subcutaneous	◯
Transdermal	◯
Intraocular	◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	24 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	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 (15)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Name of Medication	AMOXIL/CLAVULANATE
Prophylaxis	Yes ⚪
	No ⚫
Indication	APPENDICITIS
Dose per administration	875/125

Dose unit
- mg ⚫
- ug ⚪
- mL ⚪
- g ⚪
- IU ⚪
- tablet ⚪
- capsule ⚪
- puff ⚪
- Other ⚪

If dose unit is Other, specify _____

Frequency
- once daily ⚪
- twice daily ⚫
- three times daily ⚪
- four times daily ⚪
- every other day ⚪
- every week ⚪
- every month ⚪
- as needed ⚪
- once ⚪
- unknown ⚪
- other ⚪

If frequency is Other, specify _____

Route of administration
- Oral ⚫
- Topical ⚪
- Subcutaneous ⚪
- Transdermal ⚪
- Intraocular ⚪

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	24 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	1 APR 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	ZOSYN

Prophylaxis	Yes ⚪
	No ⚫

Indication	APPENDICITIS

Dose per administration	3.375

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)*	19 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	24 MAR 2021
Was this medication taken for solicited event?	Yes ⬭
	No ⬤
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬤

Name of Medication	HEPARIN DRIP

Prophylaxis	Yes ⚪
	No ⚫

Indication	ACUTE CORONARY SYNDROME

Dose per administration	6

Dose unit	mg ⚪
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚫

If dose unit is Other, specify	IV DRIP RATE VARIABLE BASED ON PTT READINGS & 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	CONTINUOUS DRIP

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)*	21 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	22 MAR 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Name of Medication	LOPRESSOR (METOPROLOL)

Prophylaxis

Yes ●

No ○

Indication	PROPHYLAXIS
Dose per administration	15

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 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ⃝
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	22 MAR 2021
Was this medication taken for solicited event?	Yes ⃝
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⃝
	803 ⃝
	804 ⃝

Name of Medication	CARVEDILOL

Prophylaxis	Yes ◯
	No ⬤

Indication	CAD
	CHF

Dose per administration	25

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	22 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ⬭
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ⬭
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬤

Name of Medication	HYDROCODONE/ACETAMINOPHEN
Prophylaxis	Yes ⭘
	No ⬤
Indication	L4 COMPRESSION FX
Dose per administration	7.5/300
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)*	24 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯

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

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

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Name of Medication	METHACARBAMOL

Prophylaxis	
	Yes ⭘
	No ⬤

Indication	L4 COMPRESSION FX
Dose per administration	750

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)*	24 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Name of Medication	MIRALAX

Prophylaxis	Yes ●
	No ○

Indication	PROPHYLAXIS
Dose per administration	17

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)*	24 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	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 (23)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Name of Medication	DOCUSATE
Prophylaxis	Yes ●
	No ○
Indication	PROPHYLAXIS
Dose per administration	100
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ●
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	24 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ⬭
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ⬭
	No ●
Separate Dosage Number (derived)	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 (24)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

Name of Medication	KCL
Prophylaxis	Yes ●
	No ○
Indication	PROPHYLAXIS
Dose per administration	10
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	MEQ
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)*	24 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

US3202179

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: ▓ (b) (4) ▓ **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Were any concomitant procedures performed?   Yes ●

                                                     No ◯

If yes, please complete Concomitant Procedures form.

US3202179

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **09 Apr 2021 15:25:27**

Generated On: 09 Jun 2021 15:46:52

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
22 MAR 2021	CARDIAC STENT PLACEMENT	Adverse Event	

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 ◯

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: ▓ (b) (4) ▓ **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

SAEID	USA-US128-2021-MRNA-1273-P30 1000013
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

SAEID	USA-US128-2021-MRNA-1273-P30 1000013
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	31/MAR/2021 09:40
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

SAEID	USA-US128-2021-MRNA-1273-P30 1000013
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/APR/2021 11:49
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

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) **22 Apr 2021 17:57:02**

Generated On: 09 Jun 2021 15:46:52

SAEID	USA-US128-2021-MRNA-1273-P30 1000013
Serious	Yes ⬤ / No ◯
Death	Yes ◯ / No ⬤
Life threatening	Yes ◯ / No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ / No ◯
Persistent or significant disability or incapacity	Yes ◯ / No ⬤
Congenital anomaly or birth defect	Yes ◯ / No ⬤
Other medically important event	Yes ◯ / No ⬤
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/APR/2021 09:19
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

SAEID	USA-US128-2021-MRNA-1273-P30 1000013
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/APR/2021 15:07
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

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form (5)
Data signed: (b) (4) **22 Apr 2021 17:57:02**
Generated On: 09 Jun 2021 15:46:52

SAEID	USA-US128-2021-MRNA-1273-P30 1000013
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/APR/2021 06:18
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

US3202179 (Prod: WR-ClinSearch, LLC)

US3202179

Form: Participant Creation

Generated On: 09 Jun 2021 15:46:52

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 21:40:48
User entered 'US3202179'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 13:19:40
	(b) (4)	

US3202179
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:18

Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 13:19:41

US3202179

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:18

US3202179
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered 'SCRN'	System	14 Aug 2020 14:18:18

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered (b) (6) 1944'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 13:19:41

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:09:59
User entered '76'	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:46:52
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered 'YEARS'	System	25 Aug 2020 19:36:54

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered '76'	System	14 Aug 2020 14:18:30

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:09:59
User entered 'Male (M)'	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:46:52

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:09:59
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:09:59
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:09:59
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:09:59
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:09:59
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:09:59
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:09:59
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:09:59
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:52

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:09:59
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:36:54

US3202179
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:46:52

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered '14 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:30

US3202179

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:52

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered 'Aug 2020'	System	14 Aug 2020 14:18:30

US3202179

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:52

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered '2020'	System	14 Aug 2020 14:18:30

US3202179

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:52

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Amendment 2 (2)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:30

US3202179

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:52

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:30

US3202179

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:52

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:30

US3202179

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:30

US3202179

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:52

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:30

US3202179

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:52

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 13:19:41

US3202179
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:46:52
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered '1'	System	14 Aug 2020 14:18:35

US3202179

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:46:52

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:35

US3202179

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:46:52

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:45:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:37:13

US3202179

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:47:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:47:53
Data point term sent to Coder	System	24 Sep 2020 21:46:12
User entered 'Migraine Headaches'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:46:07

US3202179

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'UN UNK 2000'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:46:07

US3202179

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:46:07

US3202179

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:46:07

US3202179

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:46:07

US3202179

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:46:07

US3202179

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered 'Jan 2000'	System	24 Sep 2020 21:46:07

US3202179

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered '2000'	System	24 Sep 2020 21:46:07

US3202179

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	24 Sep 2020 21:46:07

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	24 Sep 2020 21:46:07

US3202179

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:11:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:11:35
Data point term sent to Coder	System	13 Apr 2021 15:56:16
User entered 'COPD'	Teresa Deese (b) (4)	13 Apr 2021 15:55:51

US3202179

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 16:28:55
User entered empty; reason for change Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:28:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 15:55:51
User entered 'UN UNK unk' (non-conformant).	Teresa Deese (b) (4)	13 Apr 2021 15:55:51

US3202179

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '1' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:28:55
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 15:55:51

US3202179

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 15:55:51

US3202179

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 15:55:51

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 15:55:51

US3202179

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:55:51

US3202179
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:46:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:55:51

US3202179

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:55:51

US3202179

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:55:51

US3202179

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Angina pectoris - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:11:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:11:34
Data point term sent to Coder	System	13 Apr 2021 15:56:19
User entered 'angina'	Teresa Deese (b) (4)	13 Apr 2021 15:56:17

US3202179

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Apr 2021 16:38:23
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Apr 2021 16:37:29
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 16:37:29
User entered empty; reason for change Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:37:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 15:56:17
User entered 'UN UNK unk' (non-conformant).	Teresa Deese (b) (4)	13 Apr 2021 15:56:17

US3202179
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:46:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered '1' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:38:23
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 15:56:17

US3202179

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 15:56:17

US3202179

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 15:56:17

US3202179

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 15:56:17

US3202179

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:56:17

US3202179

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:56:17

US3202179

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:56:17

US3202179

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:56:17

US3202179

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
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)	13 Apr 2021 17:12:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:12:47
Data point term sent to Coder	System	13 Apr 2021 15:57:19
User entered 'hypertension'	Teresa Deese (b) (4)	13 Apr 2021 15:56:46

US3202179

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Apr 2021 16:38:36
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Apr 2021 16:38:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 16:38:32
User entered empty; reason for change Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:38:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 15:56:46
User entered 'UN UNK unk' (non-conformant).	Teresa Deese (b) (4)	13 Apr 2021 15:56:46

US3202179

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered '1' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	13 Apr 2021 16:38:36
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 15:56:46

US3202179

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 15:56:46

US3202179

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 15:56:46

US3202179

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 15:56:46

US3202179

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:56:46

US3202179

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:56:46

US3202179

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:56:46

US3202179
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:46:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:56:46

US3202179

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:12:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:12:53
Data point term sent to Coder	System	13 Apr 2021 15:58:20
User entered 'Congestive heart failure'	Teresa Deese (b) (4)	13 Apr 2021 15:57:50

US3202179
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 16:38:47
User entered empty; reason for change Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:38:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 15:57:50
User entered 'UN UNK unk' (non-conformant).	Teresa Deese (b) (4)	13 Apr 2021 15:57:50

US3202179

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered '1' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:38:47
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 15:57:50

US3202179

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 15:57:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 15:57:50

US3202179

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 15:57:50

US3202179

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:57:50

US3202179

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:57:50

US3202179

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:57:50

US3202179

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:57:50

US3202179

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:13:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:13:03
Data point term sent to Coder	System	13 Apr 2021 15:58:20
User entered 'chronic kidney disease'	Teresa Deese (b) (4)	13 Apr 2021 15:58:19

US3202179

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 16:38:59
User entered empty; reason for change Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:38:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 15:58:19
User entered 'UN UNK unk' (non-conformant).	Teresa Deese (b) (4)	13 Apr 2021 15:58:19

US3202179

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '1' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:38:59
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 15:58:19

US3202179

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 15:58:19

US3202179

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 15:58:19

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 15:58:19

FDA-CBER-2022-1614-0446469

US3202179
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:46:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:58:19

US3202179

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:58:19

US3202179

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:58:19

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 15:58:19

US3202179

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:46:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:20:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:20:25
Data point term sent to Coder	System	13 Apr 2021 16:07:34
User entered 'atrial fib'	Teresa Deese (b) (4)	13 Apr 2021 16:06:38

US3202179

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 16:39:11
User entered empty; reason for change Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:39:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Apr 2021 16:06:38
User entered 'UN UNK unk' (non-conformant).	Teresa Deese (b) (4)	13 Apr 2021 16:06:38

US3202179

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered '1' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	13 Apr 2021 16:39:11
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:06:38

US3202179

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:46:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:06:38

US3202179

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:06:38

US3202179

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:46:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:06:38

US3202179
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:46:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 16:06:38

US3202179

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:46:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 16:06:38

US3202179

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:46:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 16:06:38

US3202179
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:46:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	13 Apr 2021 16:06:38

US3202179
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:46:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:41:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:41:41
Data point term sent to Coder	System	16 Apr 2021 18:32:05
User entered 'CORONARY ARTERY DISEASE (3 STENTS)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:31:51

US3202179

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:46:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
	(b) (4)	
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	16 Apr 2021 18:31:51

US3202179

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 18:31:51

US3202179

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:46:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:31:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 18:31:51

US3202179

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:46:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 18:31:51

US3202179

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:46:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered 'Jan 2019'	System	16 Apr 2021 18:31:51

US3202179

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:46:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered '2019'	System	16 Apr 2021 18:31:51

US3202179

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:46:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	16 Apr 2021 18:31:51

US3202179

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:46:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered empty.	System	16 Apr 2021 18:31:51

US3202179

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:38:16

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:38:16

US3202179

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '09:41'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:38:16

US3202179

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered '14 Aug 2020 09:41'	System	25 Aug 2020 19:38:16

US3202179
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '178.0' cm	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:38:16
DataPoint set to visible.	System	14 Aug 2020 14:18:35

US3202179

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '101.0' kg	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:38:16
DataPoint set to visible.	System	14 Aug 2020 14:18:35

US3202179
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
Amendment Manager: User entered '31.87729'	System	16 Sep 2020 23:56:47
User entered '31.9'	System	25 Aug 2020 19:38:16
DataPoint set to visible.	System	14 Aug 2020 14:18:35

US3202179
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered 'kg/m2'	System	25 Aug 2020 19:38:16
DataPoint set to visible.	System	14 Aug 2020 14:18:35

US3202179
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:37:19
Query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:27:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:27:38
User opened query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 12:48:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 12:47:53
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 19:38:21
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 19:38:16
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:38:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:38:16

US3202179
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:38:16

US3202179
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:37:22
Query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:28:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:27:38
User opened query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 12:48:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 12:48:14
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 19:38:28
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 19:38:16
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:38:16

US3202179
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered 'bpm'	System	12 Sep 2020 19:27:38
User entered empty.	System	25 Aug 2020 19:38:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:37:31
Query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:28:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:27:38
User opened query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 12:48:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 12:48:18
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 19:38:32
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 19:38:16
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:38:16

US3202179
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered 'breaths/min'	System	12 Sep 2020 19:27:38
User entered empty.	System	25 Aug 2020 19:38:16

US3202179

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:37:34
Query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:28:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:27:38
User opened query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 12:48:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 12:48:20
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 19:38:36
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 19:38:16
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:38:16

US3202179
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered 'mmHg'	System	12 Sep 2020 19:27:38
User entered empty.	System	25 Aug 2020 19:38:16

US3202179

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:37:40
Query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:28:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:27:38
User opened query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 12:48:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 12:48:22
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 19:39:54
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 19:38:16
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:38:16

US3202179

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User entered 'mmHg'	System	12 Sep 2020 19:27:38
User entered empty.	System	25 Aug 2020 19:38:16

US3202179

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01

US3202179
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:40:19

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '14 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 19:40:19

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:46:52
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:40:57

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:52

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:40:57

US3202179

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:48

US3202179

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '14 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:48

US3202179

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

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 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:18:48

FDA-CBER-2022-1614-0446540

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'VISIT1'	System	14 Aug 2020 14:18:48

US3202179

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 13:55:02

US3202179
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:46:52

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:27:01
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:27:00
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 13:55:02
User entered '186323' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 13:55:02

US3202179

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:52

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 13:55:02

US3202179

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:52

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 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:41:58

US3202179

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:52

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 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:41:58

US3202179

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:41:58

US3202179

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:52

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:41:58

US3202179

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:52

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:41:58

US3202179

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:52

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:01:04
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:13:49

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:06:19
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:40
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:00:15
User entered '178.0' cm	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:06:21
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:40
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:00:18
User entered '101.0' kg	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:06:19
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:40
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:00:15
User entered '178.0' cm	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:06:21
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:40
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:00:18
User entered '101.0' kg	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:46:52
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '09:41'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '14 Aug 2020 09:41'	System	25 Aug 2020 19:47:37

US3202179
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:46:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:00:21
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	zackery harmon (b) (4) (b) (4)	18 Sep 2020 13:34:44
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:56:47
User entered '35.7' C	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '60'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:46:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'bpm'	System	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '21'	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'breaths/min'	System	25 Aug 2020 19:47:37

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
	(b) (4)	
User entered '151'	(b) (4), (b) (6)	25 Aug 2020 19:47:37

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'mmHg'	System	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '89'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'mmHg'	System	25 Aug 2020 19:47:37

FDA-CBER-2022-1614-0446570

US3202179
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:46:52
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:06:19
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:40
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:00:15
User entered '178.0' cm	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:46:52
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:06:21
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:33:40
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:00:18
User entered '101.0' kg	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '11:01'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '14 Aug 2020 11:01'	System	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:01:46
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	zackery harmon (b) (4) (b) (4)	18 Sep 2020 13:34:58
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:56:47
User entered '35.9' C	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
	(b) (4)	
User entered '78'	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'bpm'	System	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '16'	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'breaths/min'	System	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 12:55:27
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 19:47:52
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	25 Aug 2020 19:47:37
User entered '160'	(b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'mmHg'	System	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '94'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'mmHg'	System	25 Aug 2020 19:47:37

US3202179

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:48:20

US3202179

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '14 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 19:48:20

US3202179
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:46:52
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:47:53

US3202179
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:46:52
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:47:53

US3202179

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

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 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:47:53

US3202179
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:46:52
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 14:47:53

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:46:52

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '14 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:47:53

US3202179
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:46:52

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '10:28'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:47:53

US3202179

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '14 Aug 2020 10:28'	System	14 Aug 2020 14:47:53

US3202179

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:47:53

US3202179
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:46:52
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'ONCE'	System	14 Aug 2020 14:47:53

US3202179
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:46:52
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 14:47:53

US3202179

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:19:07

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '14 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:19:07

US3202179

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '09:52'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:19:07

US3202179

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '14 Aug 2020 09:52'	System	14 Aug 2020 14:19:07

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 15:46:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '14 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:19:22

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:46:52

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:19:22

US3202179

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:19:22

US3202179

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '09:49'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:19:22

US3202179

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '14 Aug 2020 09:49'	System	14 Aug 2020 14:19:22

US3202179

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:52

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:19:22

US3202179

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:19:22

US3202179

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:19:22

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered empty.	System	14 Aug 2020 14:19:22

US3202179

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	24 Aug 2020 21:23:33

US3202179

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '1'	System	24 Aug 2020 21:23:33

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '14 Aug 2020 10:48'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '14 Aug 2020 13:18'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '14 Aug 2020 14:13'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 2'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:46:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446637

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:46:52

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:46:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 3'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:46:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:52

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:46:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446648

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 4'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-17T17:10:50', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bc80971a-5fa7-491a-8bf0-803aafcd736f'	System	17 Aug 2020 21:12:28
User entered 'Yes (Y)'	System	17 Aug 2020 21:12:28

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-17T17:11:49', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bc80971a-5fa7-491a-8bf0-803aafcd736f'	System	17 Aug 2020 21:12:28
User entered '97.0'	System	17 Aug 2020 21:12:28

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-17T17:12:08', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bc80971a-5fa7-491a-8bf0-803aafcd736f'	System	17 Aug 2020 21:12:28
User entered 'No (N)'	System	17 Aug 2020 21:12:28

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-17T17:12:23', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bc80971a-5fa7-491a-8bf0-803aafcd736f'	System	17 Aug 2020 21:12:28
User entered '17 Aug 2020 17:12'	System	17 Aug 2020 21:12:28

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 5'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:46:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:04:06', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd976cb70-8f5e-4322-80fe-27bfad86cf8e'	System	18 Aug 2020 19:05:42
User entered 'Yes (Y)'	System	18 Aug 2020 19:05:42

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:04:31', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd976cb70-8f5e-4322-80fe-27bfad86cf8e'	System	18 Aug 2020 19:05:42
User entered '97.1'	System	18 Aug 2020 19:05:42

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:04:40', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd976cb70-8f5e-4322-80fe-27bfad86cf8e'	System	18 Aug 2020 19:05:42
User entered 'No (N)'	System	18 Aug 2020 19:05:42

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:04:59', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd976cb70-8f5e-4322-80fe-27bfad86cf8e'	System	18 Aug 2020 19:05:42
User entered '18 Aug 2020 15:04'	System	18 Aug 2020 19:05:42

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 6'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:37:48', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7ce3eb63-08d8-4d38-8006-b58bbbb5569d'	System	19 Aug 2020 22:38:12
User entered 'Yes (Y)'	System	19 Aug 2020 22:38:12

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:37:57', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7ce3eb63-08d8-4d38-8006-b58bbbb5569d'	System	19 Aug 2020 22:38:12
User entered '97.0'	System	19 Aug 2020 22:38:12

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:05', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7ce3eb63-08d8-4d38-8006-b58bbbb5569d'	System	19 Aug 2020 22:38:12
User entered 'No (N)'	System	19 Aug 2020 22:38:12

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:09', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7ce3eb63-08d8-4d38-8006-b58bbbb5569d'	System	19 Aug 2020 22:38:12
User entered '19 Aug 2020 18:38'	System	19 Aug 2020 22:38:12

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:46:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 7'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	████ (b) (4), (b) (6) ████	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:05:19', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2d6ee7e3-5a05-4069-bf12-9b2b81f0beff'	System	20 Aug 2020 22:05:49
User entered 'Yes (Y)'	System	20 Aug 2020 22:05:49

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:05:29', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2d6ee7e3-5a05-4069-bf12-9b2b81f0beff'	System	20 Aug 2020 22:05:49
User entered '98.0'	System	20 Aug 2020 22:05:49

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:05:42', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2d6ee7e3-5a05-4069-bf12-9b2b81f0beff'	System	20 Aug 2020 22:05:49
User entered 'No (N)'	System	20 Aug 2020 22:05:49

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:05:46', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2d6ee7e3-5a05-4069-bf12-9b2b81f0beff'	System	20 Aug 2020 22:05:49
User entered '20 Aug 2020 18:05'	System	20 Aug 2020 22:05:49

US3202179

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:46:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446682

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

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)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446683

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
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)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '14 Aug 2020 10:48'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '14 Aug 2020 13:18'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446692

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)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446693

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
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)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '14 Aug 2020 14:13'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 2'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:46:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:52

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)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446704

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)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 3'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:46:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:52

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)	26 Feb 2021 04:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446714

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:46:52
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)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 4'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:46:52
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)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:46:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:52

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)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 5'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T09:34:19', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'ec93b5a2-fe68-41c4-b007-e4e423c53993'	System	19 Aug 2020 13:34:40
User entered 'None (1)'	System	19 Aug 2020 13:34:40

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T09:34:24', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'ec93b5a2-fe68-41c4-b007-e4e423c53993'	System	19 Aug 2020 13:34:40
User entered 'No (N)'	System	19 Aug 2020 13:34:40

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T09:34:27', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'ec93b5a2-fe68-41c4-b007-e4e423c53993'	System	19 Aug 2020 13:34:40
User entered 'No (N)'	System	19 Aug 2020 13:34:40

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T09:34:31', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'ec93b5a2-fe68-41c4-b007-e4e423c53993'	System	19 Aug 2020 13:34:40
User entered 'None (1)'	System	19 Aug 2020 13:34:40

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T09:34:35', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'ec93b5a2-fe68-41c4-b007-e4e423c53993'	System	19 Aug 2020 13:34:40
User entered '19 Aug 2020 09:34'	System	19 Aug 2020 13:34:40

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:46:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 6'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:17', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '916f8a1d-d674-4671-b0ce-96f9d904bfbb'	System	19 Aug 2020 22:38:35
User entered 'None (1)'	System	19 Aug 2020 22:38:35

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:21', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '916f8a1d-d674-4671-b0ce-96f9d904bfbb'	System	19 Aug 2020 22:38:35
User entered 'No (N)'	System	19 Aug 2020 22:38:35

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:25', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '916f8a1d-d674-4671-b0ce-96f9d904bfbb'	System	19 Aug 2020 22:38:35
User entered 'No (N)'	System	19 Aug 2020 22:38:35

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:30', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '916f8a1d-d674-4671-b0ce-96f9d904bfbb'	System	19 Aug 2020 22:38:35
User entered 'None (1)'	System	19 Aug 2020 22:38:35

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:33', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '916f8a1d-d674-4671-b0ce-96f9d904bfbb'	System	19 Aug 2020 22:38:35
User entered '19 Aug 2020 18:38'	System	19 Aug 2020 22:38:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:46:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 7'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:05:53', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7b183940-5ad4-4d49-a648-e3c38f660ff1'	System	20 Aug 2020 22:06:13
User entered 'None (1)'	System	20 Aug 2020 22:06:13

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:05:58', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7b183940-5ad4-4d49-a648-e3c38f660ff1'	System	20 Aug 2020 22:06:13
User entered 'No (N)'	System	20 Aug 2020 22:06:13

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:06:01', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7b183940-5ad4-4d49-a648-e3c38f660ff1'	System	20 Aug 2020 22:06:13
User entered 'No (N)'	System	20 Aug 2020 22:06:13

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:06:06', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7b183940-5ad4-4d49-a648-e3c38f660ff1'	System	20 Aug 2020 22:06:13
User entered 'None (1)'	System	20 Aug 2020 22:06:13

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:06:09', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7b183940-5ad4-4d49-a648-e3c38f660ff1'	System	20 Aug 2020 22:06:13
User entered '20 Aug 2020 18:06'	System	20 Aug 2020 22:06:13

US3202179

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:46:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 14:47:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446758

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '14 Aug 2020 10:48'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '14 Aug 2020 13:18'	System	14 Aug 2020 14:47:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '14 Aug 2020 14:13'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 2'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446783

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 3'	System	14 Aug 2020 14:47:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446794

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 4'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446801

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 5'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:05:38', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd08096e0-b35e-471c-a03b-79b61cd26835'	System	18 Aug 2020 19:06:37
User entered 'None (0)'	System	18 Aug 2020 19:06:37

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:05:48', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd08096e0-b35e-471c-a03b-79b61cd26835'	System	18 Aug 2020 19:06:37
User entered 'None (0)'	System	18 Aug 2020 19:06:37

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:06:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd08096e0-b35e-471c-a03b-79b61cd26835'	System	18 Aug 2020 19:06:37
User entered 'None (0)'	System	18 Aug 2020 19:06:37

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:06:06', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd08096e0-b35e-471c-a03b-79b61cd26835'	System	18 Aug 2020 19:06:37
User entered 'None (0)'	System	18 Aug 2020 19:06:37

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:06:13', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd08096e0-b35e-471c-a03b-79b61cd26835'	System	18 Aug 2020 19:06:37
User entered 'None (0)'	System	18 Aug 2020 19:06:37

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:06:18', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd08096e0-b35e-471c-a03b-79b61cd26835'	System	18 Aug 2020 19:06:37
User entered 'None (0)'	System	18 Aug 2020 19:06:37

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:06:28', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd08096e0-b35e-471c-a03b-79b61cd26835'	System	18 Aug 2020 19:06:37
User entered 'No (N)'	System	18 Aug 2020 19:06:37

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-18T15:06:33', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd08096e0-b35e-471c-a03b-79b61cd26835'	System	18 Aug 2020 19:06:37
User entered '18 Aug 2020 15:06'	System	18 Aug 2020 19:06:37

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 6'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:41', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9576d09c-60fa-4843-b274-99aa3421033e'	System	19 Aug 2020 22:39:11
User entered 'None (0)'	System	19 Aug 2020 22:39:11

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:44', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9576d09c-60fa-4843-b274-99aa3421033e'	System	19 Aug 2020 22:39:11
User entered 'None (0)'	System	19 Aug 2020 22:39:11

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:46', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9576d09c-60fa-4843-b274-99aa3421033e'	System	19 Aug 2020 22:39:11
User entered 'None (0)'	System	19 Aug 2020 22:39:11

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:48', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9576d09c-60fa-4843-b274-99aa3421033e'	System	19 Aug 2020 22:39:11
User entered 'None (0)'	System	19 Aug 2020 22:39:11

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:50', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9576d09c-60fa-4843-b274-99aa3421033e'	System	19 Aug 2020 22:39:11
User entered 'None (0)'	System	19 Aug 2020 22:39:11

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:53', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9576d09c-60fa-4843-b274-99aa3421033e'	System	19 Aug 2020 22:39:11
User entered 'None (0)'	System	19 Aug 2020 22:39:11

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:38:58', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9576d09c-60fa-4843-b274-99aa3421033e'	System	19 Aug 2020 22:39:11
User entered 'No (N)'	System	19 Aug 2020 22:39:11

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	████ (b) (4), (b) (6) ████	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-19T18:39:06', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9576d09c-60fa-4843-b274-99aa3421033e'	System	19 Aug 2020 22:39:11
User entered '19 Aug 2020 18:39'	System	19 Aug 2020 22:39:11

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 7'	System	14 Aug 2020 14:47:53

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:06:15', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'fc36442d-ce97-45eb-87a5-22986f82f820'	System	20 Aug 2020 22:06:47
User entered 'None (0)'	System	20 Aug 2020 22:06:47

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:06:21', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'fc36442d-ce97-45eb-87a5-22986f82f820'	System	20 Aug 2020 22:06:47
User entered 'None (0)'	System	20 Aug 2020 22:06:47

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:06:24', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'fc36442d-ce97-45eb-87a5-22986f82f820'	System	20 Aug 2020 22:06:47
User entered 'None (0)'	System	20 Aug 2020 22:06:47

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:06:28', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'fc36442d-ce97-45eb-87a5-22986f82f820'	System	20 Aug 2020 22:06:47
User entered 'None (0)'	System	20 Aug 2020 22:06:47

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:06:31', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'fc36442d-ce97-45eb-87a5-22986f82f820'	System	20 Aug 2020 22:06:47
User entered 'None (0)'	System	20 Aug 2020 22:06:47

US3202179
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:06:34', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'fc36442d-ce97-45eb-87a5-22986f82f820'	System	20 Aug 2020 22:06:47
User entered 'None (0)'	System	20 Aug 2020 22:06:47

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:06:39', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'fc36442d-ce97-45eb-87a5-22986f82f820'	System	20 Aug 2020 22:06:47
User entered 'No (N)'	System	20 Aug 2020 22:06:47

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-08-20T18:06:43', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'fc36442d-ce97-45eb-87a5-22986f82f820'	System	20 Aug 2020 22:06:47
User entered '20 Aug 2020 18:06'	System	20 Aug 2020 22:06:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 14:47:53

US3202179

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 14:47:53

US3202179

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	24 Aug 2020 21:23:54

US3202179

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered '24 Aug 2020'	Lilian Nukuna (b) (4) (b) (4)	24 Aug 2020 21:23:54

Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	24 Aug 2020 21:23:54

FDA-CBER-2022-1614-0446844

US3202179

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	24 Aug 2020 21:23:54

US3202179
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	24 Aug 2020 21:24:03

US3202179
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '1'	System	24 Aug 2020 21:24:03

Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:53:25

US3202179

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered '28 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:53:25

Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Contact Not Made (CONTACT NOT MADE)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:53:25

US3202179

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'No answer'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:53:25

US3202179

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:01:12

US3202179

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '1'	System	24 Sep 2020 14:01:12

US3202179

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:53:47

US3202179

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered '4 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:53:47

US3202179

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Contact Made (CONTACT MADE)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:53:47

US3202179
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:53:47

US3202179

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:01:19

US3202179

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '1'	System	24 Sep 2020 14:01:19

US3202179
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:01:33

US3202179

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 12:58:34
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Date is correct' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:01:41
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Sep 2020 14:01:33
User entered '24 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:01:33

US3202179

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

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 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:01:33

US3202179
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'VISIT2'	System	24 Sep 2020 14:01:33

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '24 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '08:57'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered '24 Sep 2020 08:57'	System	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '36.7' C	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

FDA-CBER-2022-1614-0446870

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '78'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:46:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'bpm'	System	24 Sep 2020 21:55:58

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '14'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'breaths/min'	System	24 Sep 2020 21:55:58

FDA-CBER-2022-1614-0446875

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '157'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'mmHg'	System	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '88'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'mmHg'	System	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '24 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '10:14'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered '24 Sep 2020 10:14'	System	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '36.5' C	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 15:18:18
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per Sub I' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:56:22
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Sep 2020 21:55:58
User entered '44'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

US3202179
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:46:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'bpm'	System	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '14'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:46:52
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'breaths/min'	System	24 Sep 2020 21:55:58

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '158'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'mmHg'	System	24 Sep 2020 21:55:58

US3202179

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '88'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:55:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'mmHg'	System	24 Sep 2020 21:55:58

FDA-CBER-2022-1614-0446895

US3202179

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:01:48

US3202179

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:01:48

US3202179

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:02:14

US3202179

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:02:14

US3202179

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

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 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:02:14

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 14:02:14

US3202179

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:18:40
Query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' answered with 'OOW-Scheduling conflict between site and subject' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 13:46:32
User opened query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:15:22
User entered '24 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:02:14

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '09:38'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:02:14

US3202179

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '24 Sep 2020 09:38'	System	24 Sep 2020 14:02:14

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:02:14

FDA-CBER-2022-1614-0446905

US3202179

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'ONCE'	System	24 Sep 2020 14:02:14

US3202179

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 14:02:14

US3202179

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:22:01

US3202179

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '24 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:22:01

US3202179

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '09:04'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:22:01

US3202179

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '24 Sep 2020 09:04'	System	24 Sep 2020 15:22:01

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:46:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '24 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:21:49

US3202179

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:52

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:21:49

US3202179

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:21:49

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '09:01'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:21:49

US3202179

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '24 Sep 2020 09:01'	System	24 Sep 2020 15:21:49

US3202179

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:52

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:21:49

US3202179

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:21:49

US3202179

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:21:49

US3202179

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered empty.	System	24 Sep 2020 15:21:49

US3202179
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:02:19

US3202179
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '1'	System	24 Sep 2020 14:02:19

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446924

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446926

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '24 Sep 2020 09:58'	System	24 Sep 2020 14:02:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '24 Sep 2020 12:28'	System	24 Sep 2020 14:02:14

FDA-CBER-2022-1614-0446931

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0446933

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '24 Sep 2020 13:23'	System	24 Sep 2020 14:02:14

FDA-CBER-2022-1614-0446939

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 2'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:32:45', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '507872f5-2e82-4572-8287-97f22c9603f7'	System	25 Sep 2020 20:33:12
User entered 'Yes (Y)'	System	25 Sep 2020 20:33:12

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:32:55', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '507872f5-2e82-4572-8287-97f22c9603f7'	System	25 Sep 2020 20:33:12
User entered '98.6'	System	25 Sep 2020 20:33:12

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:04', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '507872f5-2e82-4572-8287-97f22c9603f7'	System	25 Sep 2020 20:33:12
User entered 'No (N)'	System	25 Sep 2020 20:33:12

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:09', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '507872f5-2e82-4572-8287-97f22c9603f7'	System	25 Sep 2020 20:33:12
User entered '25 Sep 2020 16:33'	System	25 Sep 2020 20:33:12

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 3'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:43:04', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '941709cf-143a-4360-a294-491bc25f723e'	System	26 Sep 2020 20:43:31
User entered 'Yes (Y)'	System	26 Sep 2020 20:43:31

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:43:16', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '941709cf-143a-4360-a294-491bc25f723e'	System	26 Sep 2020 20:43:31
User entered '97.0'	System	26 Sep 2020 20:43:31

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:43:23', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '941709cf-143a-4360-a294-491bc25f723e'	System	26 Sep 2020 20:43:31
User entered 'No (N)'	System	26 Sep 2020 20:43:31

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:43:27', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '941709cf-143a-4360-a294-491bc25f723e'	System	26 Sep 2020 20:43:31
User entered '26 Sep 2020 16:43'	System	26 Sep 2020 20:43:31

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 4'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:54:50', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '4390c86e-021c-4500-a33c-2672bd0f3246'	System	27 Sep 2020 21:55:20
User entered 'Yes (Y)'	System	27 Sep 2020 21:55:20

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:54:59', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '4390c86e-021c-4500-a33c-2672bd0f3246'	System	27 Sep 2020 21:55:20
User entered '98.0'	System	27 Sep 2020 21:55:20

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:11', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '4390c86e-021c-4500-a33c-2672bd0f3246'	System	27 Sep 2020 21:55:20
User entered 'No (N)'	System	27 Sep 2020 21:55:20

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:16', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '4390c86e-021c-4500-a33c-2672bd0f3246'	System	27 Sep 2020 21:55:20
User entered '27 Sep 2020 17:55'	System	27 Sep 2020 21:55:20

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 5'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:34:10', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bd354547-1fc3-4865-afd3-5b282086a012'	System	29 Sep 2020 13:34:38
User entered 'Yes (Y)'	System	29 Sep 2020 13:34:38

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:34:23', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bd354547-1fc3-4865-afd3-5b282086a012'	System	29 Sep 2020 13:34:38
User entered '98.0'	System	29 Sep 2020 13:34:38

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:34:32', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bd354547-1fc3-4865-afd3-5b282086a012'	System	29 Sep 2020 13:34:38
User entered 'No (N)'	System	29 Sep 2020 13:34:38

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:34:35', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bd354547-1fc3-4865-afd3-5b282086a012'	System	29 Sep 2020 13:34:38
User entered '29 Sep 2020 09:34'	System	29 Sep 2020 13:34:38

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:46:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 6'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:19:08', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1f0b4a15-8e76-4f94-b777-f6c99e17aa68'	System	29 Sep 2020 20:19:54
User entered 'Yes (Y)'	System	29 Sep 2020 20:19:54

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:19:46', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1f0b4a15-8e76-4f94-b777-f6c99e17aa68'	System	29 Sep 2020 20:19:54
User entered '98.6'	System	29 Sep 2020 20:19:54

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:19:28', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1f0b4a15-8e76-4f94-b777-f6c99e17aa68'	System	29 Sep 2020 20:19:54
User entered 'No (N)'	System	29 Sep 2020 20:19:54

FDA-CBER-2022-1614-0446972

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:19:50', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1f0b4a15-8e76-4f94-b777-f6c99e17aa68'	System	29 Sep 2020 20:19:54
User entered '29 Sep 2020 16:19'	System	29 Sep 2020 20:19:54

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 7'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:46:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:01:13', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '04e9f318-ab21-4a3b-ae59-078e5bc14790'	System	30 Sep 2020 22:01:39
User entered 'Yes (Y)'	System	30 Sep 2020 22:01:39

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:01:27', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '04e9f318-ab21-4a3b-ae59-078e5bc14790'	System	30 Sep 2020 22:01:39
User entered '98.6'	System	30 Sep 2020 22:01:39

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:46:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:01:30', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '04e9f318-ab21-4a3b-ae59-078e5bc14790'	System	30 Sep 2020 22:01:39
User entered 'No (N)'	System	30 Sep 2020 22:01:39

US3202179
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:01:34', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '04e9f318-ab21-4a3b-ae59-078e5bc14790'	System	30 Sep 2020 22:01:39
User entered '30 Sep 2020 18:01'	System	30 Sep 2020 22:01:39

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
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)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
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)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '24 Sep 2020 09:58'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '24 Sep 2020 12:28'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

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)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

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)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '24 Sep 2020 13:23'	System	24 Sep 2020 14:02:14

FDA-CBER-2022-1614-0447001

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 2'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:21', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c6cebddf-824e-4d86-be51-e86eb8bbfa0d'	System	25 Sep 2020 20:33:41
User entered 'None (1)'	System	25 Sep 2020 20:33:41

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:25', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c6cebddf-824e-4d86-be51-e86eb8bbfa0d'	System	25 Sep 2020 20:33:41
User entered 'No (N)'	System	25 Sep 2020 20:33:41

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:27', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c6cebddf-824e-4d86-be51-e86eb8bbfa0d'	System	25 Sep 2020 20:33:41
User entered 'No (N)'	System	25 Sep 2020 20:33:41

FDA-CBER-2022-1614-0447006

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:32', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c6cebddf-824e-4d86-be51-e86eb8bbfa0d'	System	25 Sep 2020 20:33:41
User entered 'None (1)'	System	25 Sep 2020 20:33:41

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:35', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c6cebddf-824e-4d86-be51-e86eb8bbfa0d'	System	25 Sep 2020 20:33:41
User entered '25 Sep 2020 16:33'	System	25 Sep 2020 20:33:41

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

FDA-CBER-2022-1614-0447009

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

FDA-CBER-2022-1614-0447010

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 3'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:43:35', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9e9960b1-d66c-4a67-97bd-a98e479b062e'	System	26 Sep 2020 20:43:55
User entered 'None (1)'	System	26 Sep 2020 20:43:55

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:46:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:43:38', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9e9960b1-d66c-4a67-97bd-a98e479b062e'	System	26 Sep 2020 20:43:55
User entered 'No (N)'	System	26 Sep 2020 20:43:55

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:43:41', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9e9960b1-d66c-4a67-97bd-a98e479b062e'	System	26 Sep 2020 20:43:55
User entered 'No (N)'	System	26 Sep 2020 20:43:55

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:43:45', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9e9960b1-d66c-4a67-97bd-a98e479b062e'	System	26 Sep 2020 20:43:55
User entered 'None (1)'	System	26 Sep 2020 20:43:55

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:43:52', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9e9960b1-d66c-4a67-97bd-a98e479b062e'	System	26 Sep 2020 20:43:55
User entered '26 Sep 2020 16:43'	System	26 Sep 2020 20:43:55

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 4'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:21', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e01a1a8a-063d-4920-aa16-b80a81ef53f4'	System	27 Sep 2020 21:55:38
User entered 'None (1)'	System	27 Sep 2020 21:55:38

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:24', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e01a1a8a-063d-4920-aa16-b80a81ef53f4'	System	27 Sep 2020 21:55:38
User entered 'No (N)'	System	27 Sep 2020 21:55:38

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:26', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e01a1a8a-063d-4920-aa16-b80a81ef53f4'	System	27 Sep 2020 21:55:38
User entered 'No (N)'	System	27 Sep 2020 21:55:38

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:29', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e01a1a8a-063d-4920-aa16-b80a81ef53f4'	System	27 Sep 2020 21:55:38
User entered 'None (1)'	System	27 Sep 2020 21:55:38

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:35', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e01a1a8a-063d-4920-aa16-b80a81ef53f4'	System	27 Sep 2020 21:55:38
User entered '27 Sep 2020 17:55'	System	27 Sep 2020 21:55:38

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:46:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:46:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 5'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:34:39', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '31050234-891a-4d9a-8464-b018ff03a202'	System	29 Sep 2020 13:34:59
User entered 'None (1)'	System	29 Sep 2020 13:34:59

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:34:43', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '31050234-891a-4d9a-8464-b018ff03a202'	System	29 Sep 2020 13:34:59
User entered 'No (N)'	System	29 Sep 2020 13:34:59

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:46:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:34:45', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '31050234-891a-4d9a-8464-b018ff03a202'	System	29 Sep 2020 13:34:59
User entered 'No (N)'	System	29 Sep 2020 13:34:59

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:34:48', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '31050234-891a-4d9a-8464-b018ff03a202'	System	29 Sep 2020 13:34:59
User entered 'None (1)'	System	29 Sep 2020 13:34:59

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:34:57', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '31050234-891a-4d9a-8464-b018ff03a202'	System	29 Sep 2020 13:34:59
User entered '29 Sep 2020 09:34'	System	29 Sep 2020 13:34:59

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:46:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 6'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:19:54', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2cbff69f-b75c-4cda-9b16-1615cac02b61'	System	29 Sep 2020 20:20:10
User entered 'None (1)'	System	29 Sep 2020 20:20:10

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:19:57', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2cbff69f-b75c-4cda-9b16-1615cac02b61'	System	29 Sep 2020 20:20:10
User entered 'No (N)'	System	29 Sep 2020 20:20:10

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:19:59', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2cbff69f-b75c-4cda-9b16-1615cac02b61'	System	29 Sep 2020 20:20:10
User entered 'No (N)'	System	29 Sep 2020 20:20:10

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:20:02', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2cbff69f-b75c-4cda-9b16-1615cac02b61'	System	29 Sep 2020 20:20:10
User entered 'None (1)'	System	29 Sep 2020 20:20:10

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:20:07', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2cbff69f-b75c-4cda-9b16-1615cac02b61'	System	29 Sep 2020 20:20:10
User entered '29 Sep 2020 16:20'	System	29 Sep 2020 20:20:10

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 7'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:02:22', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd97f8ec6-e88e-4181-91ca-cc9241847b03'	System	30 Sep 2020 22:03:36
User entered 'None (1)'	System	30 Sep 2020 22:03:36

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:02:32', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd97f8ec6-e88e-4181-91ca-cc9241847b03'	System	30 Sep 2020 22:03:36
User entered 'No (N)'	System	30 Sep 2020 22:03:36

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:02:51', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd97f8ec6-e88e-4181-91ca-cc9241847b03'	System	30 Sep 2020 22:03:36
User entered 'No (N)'	System	30 Sep 2020 22:03:36

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:03:06', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd97f8ec6-e88e-4181-91ca-cc9241847b03'	System	30 Sep 2020 22:03:36
User entered 'None (1)'	System	30 Sep 2020 22:03:36

US3202179
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:46:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:03:33', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd97f8ec6-e88e-4181-91ca-cc9241847b03'	System	30 Sep 2020 22:03:36
User entered '30 Sep 2020 18:03'	System	30 Sep 2020 22:03:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

FDA-CBER-2022-1614-0447049

US3202179

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '24 Sep 2020 09:58'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '24 Sep 2020 12:28'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

FDA-CBER-2022-1614-0447067

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:46:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '24 Sep 2020 13:23'	System	24 Sep 2020 14:02:14

FDA-CBER-2022-1614-0447071

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 2'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:46', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'af7e202d-1ce2-4005-a1cb-90f60c3ed310'	System	25 Sep 2020 20:34:10
User entered 'None (0)'	System	25 Sep 2020 20:34:10

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:49', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'af7e202d-1ce2-4005-a1cb-90f60c3ed310'	System	25 Sep 2020 20:34:10
User entered 'None (0)'	System	25 Sep 2020 20:34:10

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:51', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'af7e202d-1ce2-4005-a1cb-90f60c3ed310'	System	25 Sep 2020 20:34:10
User entered 'None (0)'	System	25 Sep 2020 20:34:10

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:54', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'af7e202d-1ce2-4005-a1cb-90f60c3ed310'	System	25 Sep 2020 20:34:10
User entered 'None (0)'	System	25 Sep 2020 20:34:10

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:56', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'af7e202d-1ce2-4005-a1cb-90f60c3ed310'	System	25 Sep 2020 20:34:10
User entered 'None (0)'	System	25 Sep 2020 20:34:10

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:33:59', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'af7e202d-1ce2-4005-a1cb-90f60c3ed310'	System	25 Sep 2020 20:34:10
User entered 'None (0)'	System	25 Sep 2020 20:34:10

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:34:03', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'af7e202d-1ce2-4005-a1cb-90f60c3ed310'	System	25 Sep 2020 20:34:10
User entered 'No (N)'	System	25 Sep 2020 20:34:10

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-25T16:34:06', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'af7e202d-1ce2-4005-a1cb-90f60c3ed310'	System	25 Sep 2020 20:34:10
User entered '25 Sep 2020 16:34'	System	25 Sep 2020 20:34:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 3'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:44:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e5c3fa16-4978-496f-8d0a-f56601c060e9'	System	26 Sep 2020 20:44:40
User entered 'None (0)'	System	26 Sep 2020 20:44:40

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:44:04', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e5c3fa16-4978-496f-8d0a-f56601c060e9'	System	26 Sep 2020 20:44:40
User entered 'None (0)'	System	26 Sep 2020 20:44:40

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:44:13', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e5c3fa16-4978-496f-8d0a-f56601c060e9'	System	26 Sep 2020 20:44:40
User entered 'None (0)'	System	26 Sep 2020 20:44:40

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:44:16', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e5c3fa16-4978-496f-8d0a-f56601c060e9'	System	26 Sep 2020 20:44:40
User entered 'None (0)'	System	26 Sep 2020 20:44:40

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:44:19', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e5c3fa16-4978-496f-8d0a-f56601c060e9'	System	26 Sep 2020 20:44:40
User entered 'None (0)'	System	26 Sep 2020 20:44:40

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:44:22', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e5c3fa16-4978-496f-8d0a-f56601c060e9'	System	26 Sep 2020 20:44:40
User entered 'None (0)'	System	26 Sep 2020 20:44:40

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:44:33', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e5c3fa16-4978-496f-8d0a-f56601c060e9'	System	26 Sep 2020 20:44:40
User entered 'No (N)'	System	26 Sep 2020 20:44:40

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:46:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-26T16:44:36', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e5c3fa16-4978-496f-8d0a-f56601c060e9'	System	26 Sep 2020 20:44:40
User entered '26 Sep 2020 16:44'	System	26 Sep 2020 20:44:40

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 4'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:39', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'b08a71a0-24fe-4c20-a036-c122b2fb4fdd'	System	27 Sep 2020 21:56:09
User entered 'None (0)'	System	27 Sep 2020 21:56:09

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:42', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'b08a71a0-24fe-4c20-a036-c122b2fb4fdd'	System	27 Sep 2020 21:56:09
User entered 'None (0)'	System	27 Sep 2020 21:56:09

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:44', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'b08a71a0-24fe-4c20-a036-c122b2fb4fdd'	System	27 Sep 2020 21:56:09
User entered 'None (0)'	System	27 Sep 2020 21:56:09

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:47', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'b08a71a0-24fe-4c20-a036-c122b2fb4fdd'	System	27 Sep 2020 21:56:09
User entered 'None (0)'	System	27 Sep 2020 21:56:09

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:50', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'b08a71a0-24fe-4c20-a036-c122b2fb4fdd'	System	27 Sep 2020 21:56:09
User entered 'None (0)'	System	27 Sep 2020 21:56:09

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:53', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'b08a71a0-24fe-4c20-a036-c122b2fb4fdd'	System	27 Sep 2020 21:56:09
User entered 'None (0)'	System	27 Sep 2020 21:56:09

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:55:58', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'b08a71a0-24fe-4c20-a036-c122b2fb4fdd'	System	27 Sep 2020 21:56:09
User entered 'No (N)'	System	27 Sep 2020 21:56:09

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-27T17:56:05', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'b08a71a0-24fe-4c20-a036-c122b2fb4fdd'	System	27 Sep 2020 21:56:09
User entered '27 Sep 2020 17:56'	System	27 Sep 2020 21:56:09

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:46:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 5'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:35:01', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bce9e055-5ec4-40de-baad-f5bffd69ce1a'	System	29 Sep 2020 13:35:24
User entered 'None (0)'	System	29 Sep 2020 13:35:24

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:35:03', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bce9e055-5ec4-40de-baad-f5bffd69ce1a'	System	29 Sep 2020 13:35:24
User entered 'None (0)'	System	29 Sep 2020 13:35:24

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:35:05', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bce9e055-5ec4-40de-baad-f5bffd69ce1a'	System	29 Sep 2020 13:35:24
User entered 'None (0)'	System	29 Sep 2020 13:35:24

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:35:08', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bce9e055-5ec4-40de-baad-f5bffd69ce1a'	System	29 Sep 2020 13:35:24
User entered 'None (0)'	System	29 Sep 2020 13:35:24

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:35:10', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bce9e055-5ec4-40de-baad-f5bffd69ce1a'	System	29 Sep 2020 13:35:24
User entered 'None (0)'	System	29 Sep 2020 13:35:24

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:35:12', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bce9e055-5ec4-40de-baad-f5bffd69ce1a'	System	29 Sep 2020 13:35:24
User entered 'None (0)'	System	29 Sep 2020 13:35:24

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:46:52
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:35:16', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bce9e055-5ec4-40de-baad-f5bffd69ce1a'	System	29 Sep 2020 13:35:24
User entered 'No (N)'	System	29 Sep 2020 13:35:24

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T09:35:19', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'bce9e055-5ec4-40de-baad-f5bffd69ce1a'	System	29 Sep 2020 13:35:24
User entered '29 Sep 2020 09:35'	System	29 Sep 2020 13:35:24

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 6'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:20:10', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1cd221e2-c3b4-4655-9c5c-6d0c6d47ce37'	System	29 Sep 2020 20:20:36
User entered 'None (0)'	System	29 Sep 2020 20:20:36

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:20:13', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1cd221e2-c3b4-4655-9c5c-6d0c6d47ce37'	System	29 Sep 2020 20:20:36
User entered 'None (0)'	System	29 Sep 2020 20:20:36

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:20:15', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1cd221e2-c3b4-4655-9c5c-6d0c6d47ce37'	System	29 Sep 2020 20:20:36
User entered 'None (0)'	System	29 Sep 2020 20:20:36

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:20:17', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1cd221e2-c3b4-4655-9c5c-6d0c6d47ce37'	System	29 Sep 2020 20:20:36
User entered 'None (0)'	System	29 Sep 2020 20:20:36

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:46:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:20:19', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1cd221e2-c3b4-4655-9c5c-6d0c6d47ce37'	System	29 Sep 2020 20:20:36
User entered 'None (0)'	System	29 Sep 2020 20:20:36

FDA-CBER-2022-1614-0447122

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:20:21', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1cd221e2-c3b4-4655-9c5c-6d0c6d47ce37'	System	29 Sep 2020 20:20:36
User entered 'None (0)'	System	29 Sep 2020 20:20:36

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:20:26', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1cd221e2-c3b4-4655-9c5c-6d0c6d47ce37'	System	29 Sep 2020 20:20:36
User entered 'No (N)'	System	29 Sep 2020 20:20:36

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-29T16:20:31', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '1cd221e2-c3b4-4655-9c5c-6d0c6d47ce37'	System	29 Sep 2020 20:20:36
User entered '29 Sep 2020 16:20'	System	29 Sep 2020 20:20:36

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	24 Sep 2020 14:02:14
User entered 'Day 7'	System	24 Sep 2020 14:02:14

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:01:41', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd2354f93-8a6d-4580-af6c-a71b7c6a4821'	System	30 Sep 2020 22:02:23
User entered 'None (0)'	System	30 Sep 2020 22:02:23

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:01:43', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd2354f93-8a6d-4580-af6c-a71b7c6a4821'	System	30 Sep 2020 22:02:23
User entered 'None (0)'	System	30 Sep 2020 22:02:23

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:01:45', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd2354f93-8a6d-4580-af6c-a71b7c6a4821'	System	30 Sep 2020 22:02:23
User entered 'None (0)'	System	30 Sep 2020 22:02:23

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:01:47', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd2354f93-8a6d-4580-af6c-a71b7c6a4821'	System	30 Sep 2020 22:02:23
User entered 'None (0)'	System	30 Sep 2020 22:02:23

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:01:49', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd2354f93-8a6d-4580-af6c-a71b7c6a4821'	System	30 Sep 2020 22:02:23
User entered 'None (0)'	System	30 Sep 2020 22:02:23

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:01:59', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd2354f93-8a6d-4580-af6c-a71b7c6a4821'	System	30 Sep 2020 22:02:23
User entered 'None (0)'	System	30 Sep 2020 22:02:23

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:02:04', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd2354f93-8a6d-4580-af6c-a71b7c6a4821'	System	30 Sep 2020 22:02:23
User entered 'No (N)'	System	30 Sep 2020 22:02:23

US3202179

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-09-30T18:02:11', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'd2354f93-8a6d-4580-af6c-a71b7c6a4821'	System	30 Sep 2020 22:02:23
User entered '30 Sep 2020 18:02'	System	30 Sep 2020 22:02:23

US3202179
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:46:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 14:02:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 14:02:14

US3202179
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	01 Oct 2020 13:07:23

US3202179

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered '1 Oct 2020'	Lilian Nukuna (b) (4) (b) (4)	01 Oct 2020 13:07:23

US3202179

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	01 Oct 2020 13:07:23

US3202179
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	01 Oct 2020 13:07:23

US3202179
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	01 Oct 2020 13:07:29

US3202179
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '1'	System	01 Oct 2020 13:07:29

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	08 Oct 2020 19:03:22

US3202179

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered '8 Oct 2020'	Lilian Nukuna (b) (4) (b) (4)	08 Oct 2020 19:03:22

Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	08 Oct 2020 19:03:22

FDA-CBER-2022-1614-0447147

US3202179
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	08 Oct 2020 19:03:22

US3202179
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	08 Oct 2020 19:03:27

US3202179

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '1'	System	08 Oct 2020 19:03:27

US3202179
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	15 Oct 2020 14:05:44

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered '15 Oct 2020'	Lilian Nukuna (b) (4) (b) (4)	15 Oct 2020 14:05:44

FDA-CBER-2022-1614-0447152

Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	15 Oct 2020 14:05:44

FDA-CBER-2022-1614-0447153

US3202179
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	15 Oct 2020 14:05:44

US3202179
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:09:59
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	15 Oct 2020 14:05:50

US3202179
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '1'	System	15 Oct 2020 14:05:50

Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Oct 2020 18:29:41

FDA-CBER-2022-1614-0447157

US3202179

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '23 Oct 2020'	Teresa Deese (b) (4)	26 Oct 2020 18:29:41

US3202179

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

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 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	26 Oct 2020 18:29:41

US3202179
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'VISIT3'	System	26 Oct 2020 18:29:41

US3202179

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Oct 2020 18:30:06

US3202179

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '23 Oct 2020'	Teresa Deese (b) (4)	26 Oct 2020 18:30:06

US3202179

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '08:41'	Teresa Deese (b) (4)	26 Oct 2020 18:30:06

US3202179
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered '23 Oct 2020 08:41'	System	26 Oct 2020 18:30:06

US3202179

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '36.4' C	Teresa Deese (b) (4)	26 Oct 2020 18:30:06

US3202179
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	26 Oct 2020 18:30:06

US3202179
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Teresa Deese (b) (4)	26 Oct 2020 18:30:06

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Oct 2020 18:30:25
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	26 Oct 2020 18:30:25
User entered '60' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Oct 2020 18:30:25
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Oct 2020 18:30:06
User entered '16'	Teresa Deese (b) (4)	26 Oct 2020 18:30:06

FDA-CBER-2022-1614-0447168

US3202179
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'bpm'	System	26 Oct 2020 18:30:06

US3202179
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Oct 2020 18:30:25
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	26 Oct 2020 18:30:25
User entered '16' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Oct 2020 18:30:25
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Oct 2020 18:30:06
User entered '60'	Teresa Deese (b) (4)	26 Oct 2020 18:30:06

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'breaths/min'	System	26 Oct 2020 18:30:06

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '147'	Teresa Deese (b) (4)	26 Oct 2020 18:30:06

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'mmHg'	System	26 Oct 2020 18:30:06

FDA-CBER-2022-1614-0447173

US3202179

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered '90'	Teresa Deese (b) (4)	26 Oct 2020 18:30:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered 'mmHg'	System	26 Oct 2020 18:30:06

FDA-CBER-2022-1614-0447175

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45

US3202179

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'No (N)'	Teresa Deese (b) (4)	26 Oct 2020 18:30:12

US3202179

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered empty.	Teresa Deese (b) (4)	26 Oct 2020 18:30:12

US3202179

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Oct 2020 18:30:40

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '23 Oct 2020'	Teresa Deese (b) (4)	26 Oct 2020 18:30:40

FDA-CBER-2022-1614-0447181

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered '08:51'	Teresa Deese (b) (4)	26 Oct 2020 18:30:40

US3202179

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered '23 Oct 2020 08:51'	System	26 Oct 2020 18:30:40

US3202179

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:03
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Oct 2020 18:30:44

US3202179

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:36:45
User entered '1'	System	26 Oct 2020 18:30:44

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 64'	System	14 Aug 2020 14:47:53

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19
Data entry locked.	System	14 Aug 2020 14:47:53
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 14:47:53

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:06:19
Data entry locked.	System	14 Aug 2020 14:47:53
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 71'	System	14 Aug 2020 14:47:53

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-10-23T17:06:49', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '873ba9c7-4af4-4394-b5ec-ec40985eeee9'	System	23 Oct 2020 21:07:13
User entered 'No (N)'	System	23 Oct 2020 21:07:13

FDA-CBER-2022-1614-0447215

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-10-23T17:07:04', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '873ba9c7-4af4-4394-b5ec-ec40985eeee9'	System	23 Oct 2020 21:07:13
User entered 'No (N)'	System	23 Oct 2020 21:07:13

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-10-23T17:07:10', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '873ba9c7-4af4-4394-b5ec-ec40985eeee9'	System	23 Oct 2020 21:07:13
User entered '23 Oct 2020 17:07:10'	System	23 Oct 2020 21:07:13

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 14:47:53

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 78'	System	14 Aug 2020 14:47:53

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-10-28T15:55:54', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '03035ff0-87ea-4b06-9873-1f3249847fea'	System	28 Oct 2020 19:56:12
User entered 'No (N)'	System	28 Oct 2020 19:56:12

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-10-28T15:56:01', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '03035ff0-87ea-4b06-9873-1f3249847fea'	System	28 Oct 2020 19:56:12
User entered 'No (N)'	System	28 Oct 2020 19:56:12

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-10-28T15:56:06', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '03035ff0-87ea-4b06-9873-1f3249847fea'	System	28 Oct 2020 19:56:12
User entered '28 Oct 2020 15:56:06'	System	28 Oct 2020 19:56:12

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 14:47:53

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 92'	System	14 Aug 2020 14:47:53

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-11T15:23:19', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '0171990c-2512-48fd-bb80-bd630da73ff4'	System	11 Nov 2020 20:23:39
User entered 'No (N)'	System	11 Nov 2020 20:23:39

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-11T15:23:27', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '0171990c-2512-48fd-bb80-bd630da73ff4'	System	11 Nov 2020 20:23:39
User entered 'No (N)'	System	11 Nov 2020 20:23:39

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-11T15:23:31', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '0171990c-2512-48fd-bb80-bd630da73ff4'	System	11 Nov 2020 20:23:39
User entered '11 Nov 2020 15:23:31'	System	11 Nov 2020 20:23:39

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 14:47:53

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 14:47:53

US3202179
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered 'Day 99'	System	14 Aug 2020 14:47:53

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-18T14:33:39', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c1e74062-3aba-48d0-a971-bc157ff021bd'	System	18 Nov 2020 19:33:52
User entered 'No (N)'	System	18 Nov 2020 19:33:52

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-18T14:33:45', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c1e74062-3aba-48d0-a971-bc157ff021bd'	System	18 Nov 2020 19:33:52
User entered 'No (N)'	System	18 Nov 2020 19:33:52

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-18T14:33:49', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c1e74062-3aba-48d0-a971-bc157ff021bd'	System	18 Nov 2020 19:33:52
User entered '18 Nov 2020 14:33:49'	System	18 Nov 2020 19:33:52

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 14:47:53

US3202179

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:02
Data entry locked.	System	14 Aug 2020 14:47:53
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 14:47:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:06:19

FDA-CBER-2022-1614-0447238

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-25T14:13:17', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '3ff43c28-4c99-4653-9be1-f3ef7f1c04ed'	System	25 Nov 2020 19:13:30
User entered 'No (N)'	System	25 Nov 2020 19:13:30

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-25T14:13:23', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '3ff43c28-4c99-4653-9be1-f3ef7f1c04ed'	System	25 Nov 2020 19:13:30
User entered 'No (N)'	System	25 Nov 2020 19:13:30

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-25T14:13:27', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '3ff43c28-4c99-4653-9be1-f3ef7f1c04ed'	System	25 Nov 2020 19:13:30
User entered '25 Nov 2020 14:13:27'	System	25 Nov 2020 19:13:30

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-29T12:33:37', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '50ffa9ae-e2be-4c14-ae5e-9b80159bb59b'	System	29 Nov 2020 17:33:52
User entered 'No (N)'	System	29 Nov 2020 17:33:52

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-29T12:33:44', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '50ffa9ae-e2be-4c14-ae5e-9b80159bb59b'	System	29 Nov 2020 17:33:52
User entered 'No (N)'	System	29 Nov 2020 17:33:52

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-11-29T12:33:48', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '50ffa9ae-e2be-4c14-ae5e-9b80159bb59b'	System	29 Nov 2020 17:33:52
User entered '29 Nov 2020 12:33:48'	System	29 Nov 2020 17:33:52

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-06T17:13:50', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'a8ec8a03-6264-4a0d-8194-3823a53e6c2f'	System	06 Dec 2020 22:14:01
User entered 'No (N)'	System	06 Dec 2020 22:14:01

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-06T17:13:55', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'a8ec8a03-6264-4a0d-8194-3823a53e6c2f'	System	06 Dec 2020 22:14:01
User entered 'No (N)'	System	06 Dec 2020 22:14:01

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-06T17:14:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'a8ec8a03-6264-4a0d-8194-3823a53e6c2f'	System	06 Dec 2020 22:14:01
User entered '06 Dec 2020 17:14:00'	System	06 Dec 2020 22:14:01

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-13T12:52:41', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '5abb5742-3116-4576-b85e-ff99d4d6a337'	System	13 Dec 2020 17:52:57
User entered 'No (N)'	System	13 Dec 2020 17:52:57

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-13T12:52:47', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '5abb5742-3116-4576-b85e-ff99d4d6a337'	System	13 Dec 2020 17:52:57
User entered 'No (N)'	System	13 Dec 2020 17:52:57

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-13T12:52:53', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '5abb5742-3116-4576-b85e-ff99d4d6a337'	System	13 Dec 2020 17:52:57
User entered '13 Dec 2020 12:52:53'	System	13 Dec 2020 17:52:57

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:06:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:06:19

FDA-CBER-2022-1614-0447261

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-20T17:49:26', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f789d459-2da2-457d-aca9-3da1c622aff1'	System	20 Dec 2020 22:49:39
User entered 'No (N)'	System	20 Dec 2020 22:49:39

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-20T17:49:32', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f789d459-2da2-457d-aca9-3da1c622aff1'	System	20 Dec 2020 22:49:39
User entered 'No (N)'	System	20 Dec 2020 22:49:39

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-20T17:49:35', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f789d459-2da2-457d-aca9-3da1c622aff1'	System	20 Dec 2020 22:49:39
User entered '20 Dec 2020 17:49:35'	System	20 Dec 2020 22:49:39

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-27T14:07:19', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '5482e44e-305a-4902-b2db-a7446aa1fe97'	System	27 Dec 2020 19:07:29
User entered 'No (N)'	System	27 Dec 2020 19:07:29

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-27T14:07:23', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '5482e44e-305a-4902-b2db-a7446aa1fe97'	System	27 Dec 2020 19:07:29
User entered 'No (N)'	System	27 Dec 2020 19:07:29

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2020-12-27T14:07:27', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '5482e44e-305a-4902-b2db-a7446aa1fe97'	System	27 Dec 2020 19:07:29
User entered '27 Dec 2020 14:07:27'	System	27 Dec 2020 19:07:29

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-03T16:20:18', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c8c92851-395f-4706-9a9a-232f544aa020'	System	03 Jan 2021 21:20:54
User entered 'No (N)'	System	03 Jan 2021 21:20:54

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-03T16:20:28', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c8c92851-395f-4706-9a9a-232f544aa020'	System	03 Jan 2021 21:20:54
User entered 'No (N)'	System	03 Jan 2021 21:20:54

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-03T16:20:51', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c8c92851-395f-4706-9a9a-232f544aa020'	System	03 Jan 2021 21:20:54
User entered '03 Jan 2021 16:20:51'	System	03 Jan 2021 21:20:54

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-10T11:57:55', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '6f1c97fa-a4f5-44d1-ad9a-4c6a4d06028e'	System	10 Jan 2021 16:58:06
User entered 'No (N)'	System	10 Jan 2021 16:58:06

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-10T11:58:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '6f1c97fa-a4f5-44d1-ad9a-4c6a4d06028e'	System	10 Jan 2021 16:58:06
User entered 'No (N)'	System	10 Jan 2021 16:58:06

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-10T11:58:04', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '6f1c97fa-a4f5-44d1-ad9a-4c6a4d06028e'	System	10 Jan 2021 16:58:06
User entered '10 Jan 2021 11:58:04'	System	10 Jan 2021 16:58:06

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-20T11:50:11', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7f620595-a26a-4fbc-a582-c622e30f08a3'	System	20 Jan 2021 16:50:24
User entered 'No (N)'	System	20 Jan 2021 16:50:24

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-20T11:50:17', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7f620595-a26a-4fbc-a582-c622e30f08a3'	System	20 Jan 2021 16:50:24
User entered 'No (N)'	System	20 Jan 2021 16:50:24

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-20T11:50:21', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '7f620595-a26a-4fbc-a582-c622e30f08a3'	System	20 Jan 2021 16:50:24
User entered '20 Jan 2021 11:50:21'	System	20 Jan 2021 16:50:24

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-24T18:28:55', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '577b36b5-90c7-4873-8e6c-044e9cf3f9a1'	System	24 Jan 2021 23:29:06
User entered 'No (N)'	System	24 Jan 2021 23:29:06

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-24T18:29:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '577b36b5-90c7-4873-8e6c-044e9cf3f9a1'	System	24 Jan 2021 23:29:06
User entered 'No (N)'	System	24 Jan 2021 23:29:06

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-24T18:29:03', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '577b36b5-90c7-4873-8e6c-044e9cf3f9a1'	System	24 Jan 2021 23:29:06
User entered '24 Jan 2021 18:29:03'	System	24 Jan 2021 23:29:06

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-31T14:52:49', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '80ddbce1-1b15-46cc-8899-1ef5d456869f'	System	31 Jan 2021 19:53:03
User entered 'No (N)'	System	31 Jan 2021 19:53:03

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-31T14:52:55', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '80ddbce1-1b15-46cc-8899-1ef5d456869f'	System	31 Jan 2021 19:53:03
User entered 'No (N)'	System	31 Jan 2021 19:53:03

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-01-31T14:52:59', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '80ddbce1-1b15-46cc-8899-1ef5d456869f'	System	31 Jan 2021 19:53:03
User entered '31 Jan 2021 14:52:59'	System	31 Jan 2021 19:53:03

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-09T18:24:47', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e2c366b9-8614-431b-a873-f8e2f8624688'	System	09 Feb 2021 23:25:03
User entered 'No (N)'	System	09 Feb 2021 23:25:03

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-09T18:24:50', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e2c366b9-8614-431b-a873-f8e2f8624688'	System	09 Feb 2021 23:25:03
User entered 'No (N)'	System	09 Feb 2021 23:25:03

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-09T18:24:54', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'e2c366b9-8614-431b-a873-f8e2f8624688'	System	09 Feb 2021 23:25:03
User entered '09 Feb 2021 18:24:54'	System	09 Feb 2021 23:25:03

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-14T14:51:12', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c3577f78-c040-4a5a-87af-aa0cafbb53dd'	System	14 Feb 2021 19:51:22
User entered 'No (N)'	System	14 Feb 2021 19:51:22

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-14T14:51:14', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c3577f78-c040-4a5a-87af-aa0cafbb53dd'	System	14 Feb 2021 19:51:22
User entered 'No (N)'	System	14 Feb 2021 19:51:22

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-14T14:51:19', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c3577f78-c040-4a5a-87af-aa0cafbb53dd'	System	14 Feb 2021 19:51:22
User entered '14 Feb 2021 14:51:19'	System	14 Feb 2021 19:51:22

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-21T14:11:59', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c0378655-265e-485c-8265-a58b3c8474c5'	System	21 Feb 2021 19:12:11
User entered 'No (N)'	System	21 Feb 2021 19:12:11

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-21T14:12:03', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c0378655-265e-485c-8265-a58b3c8474c5'	System	21 Feb 2021 19:12:11
User entered 'No (N)'	System	21 Feb 2021 19:12:11

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-21T14:12:08', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c0378655-265e-485c-8265-a58b3c8474c5'	System	21 Feb 2021 19:12:11
User entered '21 Feb 2021 14:12:08'	System	21 Feb 2021 19:12:11

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-28T12:57:39-05:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '04e28221-edb5-4617-8ff3-711011e2b214'	System	28 Feb 2021 17:57:52
User entered 'No (N)'	System	28 Feb 2021 17:57:52

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-28T12:57:42-05:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '04e28221-edb5-4617-8ff3-711011e2b214'	System	28 Feb 2021 17:57:52
User entered 'No (N)'	System	28 Feb 2021 17:57:52

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-28T12:57:48-05:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '04e28221-edb5-4617-8ff3-711011e2b214'	System	28 Feb 2021 17:57:52
User entered '28 Feb 2021 17:57:48'	System	28 Feb 2021 17:57:52

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-07T14:29:30-05:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'dd7bcb5a-a294-4754-ace8-ba1a5bda51e7'	System	07 Mar 2021 19:29:44
User entered 'No (N)'	System	07 Mar 2021 19:29:44

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-07T14:29:36-05:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'dd7bcb5a-a294-4754-ace8-ba1a5bda51e7'	System	07 Mar 2021 19:29:44
User entered 'No (N)'	System	07 Mar 2021 19:29:44

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-07T14:29:40-05:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'dd7bcb5a-a294-4754-ace8-ba1a5bda51e7'	System	07 Mar 2021 19:29:44
User entered '07 Mar 2021 14:29:40'	System	07 Mar 2021 19:29:44

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-14T14:53:47-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9cfed9ca-ab09-49f7-a707-457e3e211f71'	System	14 Mar 2021 18:54:09
User entered 'No (N)'	System	14 Mar 2021 18:54:09

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-14T14:53:53-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9cfed9ca-ab09-49f7-a707-457e3e211f71'	System	14 Mar 2021 18:54:09
User entered 'No (N)'	System	14 Mar 2021 18:54:09

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-14T14:54:02-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '9cfed9ca-ab09-49f7-a707-457e3e211f71'	System	14 Mar 2021 18:54:09
User entered '14 Mar 2021 14:54:02'	System	14 Mar 2021 18:54:09

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-28T15:46:18-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f1ac1fb9-9d92-470c-952e-981f68506dab'	System	28 Mar 2021 19:47:20
User entered 'Yes (Y)'	System	28 Mar 2021 19:47:20

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-28T15:46:25-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f1ac1fb9-9d92-470c-952e-981f68506dab'	System	28 Mar 2021 19:47:20
User entered 'No (N)'	System	28 Mar 2021 19:47:20

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-28T15:46:33-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f1ac1fb9-9d92-470c-952e-981f68506dab'	System	28 Mar 2021 19:47:20
User entered 'No (N)'	System	28 Mar 2021 19:47:20

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-28T15:46:52-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f1ac1fb9-9d92-470c-952e-981f68506dab'	System	28 Mar 2021 19:47:20
User entered 'Yes (Y)'	System	28 Mar 2021 19:47:20

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Please 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-28T15:47:06-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f1ac1fb9-9d92-470c-952e-981f68506dab'	System	28 Mar 2021 19:47:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Mar 2021 19:47:20

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-03-28T15:47:10-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f1ac1fb9-9d92-470c-952e-981f68506dab'	System	28 Mar 2021 19:47:20
User entered '28 Mar 2021 15:47:10'	System	28 Mar 2021 19:47:20

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:06:19

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-04T13:12:54-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '002f2bba-0c1c-4e52-9fcf-20f40e816faa'	System	04 Apr 2021 17:13:04
User entered 'No (N)'	System	04 Apr 2021 17:13:04

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-04T13:12:56-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '002f2bba-0c1c-4e52-9fcf-20f40e816faa'	System	04 Apr 2021 17:13:04
User entered 'No (N)'	System	04 Apr 2021 17:13:04

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-04T13:13:02-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '002f2bba-0c1c-4e52-9fcf-20f40e816faa'	System	04 Apr 2021 17:13:04
User entered '04 Apr 2021 13:13:02'	System	04 Apr 2021 17:13:04

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-11T15:49:52-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2a2c365e-8259-4071-b40c-7a5d7b119a3d'	System	11 Apr 2021 19:50:08
User entered 'No (N)'	System	11 Apr 2021 19:50:08

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-11T15:49:55-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2a2c365e-8259-4071-b40c-7a5d7b119a3d'	System	11 Apr 2021 19:50:08
User entered 'No (N)'	System	11 Apr 2021 19:50:08

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-11T15:49:59-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: '2a2c365e-8259-4071-b40c-7a5d7b119a3d'	System	11 Apr 2021 19:50:08
User entered '11 Apr 2021 15:49:59'	System	11 Apr 2021 19:50:08

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-18T17:09:49-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f423bb0f-5986-42db-a810-985eb2c7c469'	System	18 Apr 2021 21:10:02
User entered 'No (N)'	System	18 Apr 2021 21:10:02

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-18T17:09:52-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f423bb0f-5986-42db-a810-985eb2c7c469'	System	18 Apr 2021 21:10:02
User entered 'No (N)'	System	18 Apr 2021 21:10:02

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-18T17:09:56-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'f423bb0f-5986-42db-a810-985eb2c7c469'	System	18 Apr 2021 21:10:02
User entered '18 Apr 2021 17:09:56'	System	18 Apr 2021 21:10:02

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-25T12:41:42-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'af9a4d8d-98cd-4497-980a-34ad5903f872'	System	25 Apr 2021 16:42:02
User entered 'No (N)'	System	25 Apr 2021 16:42:02

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-25T12:41:46-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'af9a4d8d-98cd-4497-980a-34ad5903f872'	System	25 Apr 2021 16:42:02
User entered 'No (N)'	System	25 Apr 2021 16:42:02

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-04-25T12:41:59-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'af9a4d8d-98cd-4497-980a-34ad5903f872'	System	25 Apr 2021 16:42:02
User entered '25 Apr 2021 12:41:59'	System	25 Apr 2021 16:42:02

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-05-02T14:17:36-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'a30dc524-7724-4075-b6db-1438ef718cd8'	System	02 May 2021 18:17:48
User entered 'No (N)'	System	02 May 2021 18:17:48

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Have you been exposed to someone with 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 (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-05-02T14:17:41-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'a30dc524-7724-4075-b6db-1438ef718cd8'	System	02 May 2021 18:17:48
User entered 'No (N)'	System	02 May 2021 18:17:48

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-05-02T14:17:44-04:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'a30dc524-7724-4075-b6db-1438ef718cd8'	System	02 May 2021 18:17:48
User entered '02 May 2021 14:17:44'	System	02 May 2021 18:17:48

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:06:19

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:06:19

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:06:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:06:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:06:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:06:19

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:06:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:06:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:06:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:06:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:06:19

FDA-CBER-2022-1614-0447547

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:06:19

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:06:19

FDA-CBER-2022-1614-0447587

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:06:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:06:19

FDA-CBER-2022-1614-0447595

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:06:19

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:06:19

US3202179
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:46:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:06:19

US3202179

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:06:19
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:06:19

US3202179

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:46:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-28T12:57:24-05:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c60fb3a8-6d57-4df6-bdc1-aab607334de3'	System	28 Feb 2021 17:57:30
User entered 'No (N)'	System	28 Feb 2021 17:57:30

US3202179

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:46:52

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:37:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89F43AE5-9163-43B4-8915-9A83CE292FAD)', Time: '2021-02-28T12:57:28-05:00', User OID: 'PatientReportedOutcome (US3202179)', ODM File OID: 'c60fb3a8-6d57-4df6-bdc1-aab607334de3'	System	28 Feb 2021 17:57:30
User entered '28 Feb 2021 17:57:28'	System	28 Feb 2021 17:57:30

US3202179
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	26 Mar 2021 12:44:16
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	13 Nov 2020 20:43:18

US3202179
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	26 Mar 2021 12:44:16
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 21:14:34
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'scheduled' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	13 Nov 2020 20:43:48
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	13 Nov 2020 20:43:18
User entered '13 Nov 2020'	Lilian Nukuna (b) (4) (b) (4)	13 Nov 2020 20:43:18

US3202179

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	26 Mar 2021 12:44:16
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	13 Nov 2020 20:43:18

US3202179
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	26 Mar 2021 12:44:16
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	13 Nov 2020 20:43:18

US3202179

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	26 Mar 2021 12:44:16
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	13 Nov 2020 20:43:56

US3202179
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:35:59
User entered '1'	System	13 Nov 2020 20:43:56

US3202179

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 18:35:01

Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:35:01

US3202179

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:35:01

US3202179
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:35:01

US3202179
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 18:35:04

US3202179
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User entered '1'	System	15 Dec 2020 18:35:04

US3202179

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	15 Jan 2021 22:01:30

US3202179

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	18 Jan 2021 09:22:08
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'scheduled' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	15 Jan 2021 22:01:56
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	15 Jan 2021 22:01:30
User entered '15 Jan 2021'	Lilian Nukuna (b) (4) (b) (4)	15 Jan 2021 22:01:30

US3202179

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lilian Nukuna (b) (4) (b) (4)	15 Jan 2021 22:01:30

US3202179

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'left a voice message'	Lilian Nukuna (b) (4) (b) (4)	15 Jan 2021 22:01:30

US3202179
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	15 Jan 2021 22:02:03

US3202179

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User entered '1'	System	15 Jan 2021 22:02:03

US3202179
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 20:03:46

US3202179

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 11:58:00
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Missed call' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 20:05:38
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Feb 2021 20:03:46
User entered '15 Feb 2021'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 20:03:46

US3202179

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 20:03:46

US3202179
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'left a voice message. Subject called back on 19Feb. 2021'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 20:03:46

US3202179
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 20:05:46

US3202179
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:22:55
User entered '1'	System	19 Feb 2021 20:05:46

US3202179
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 18:06:50

US3202179
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered '30 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 18:06:50

US3202179

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

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 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered 'Clinic (Clinic)'	Erica Osmundsen (b) (4)	30 Mar 2021 18:06:50

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User entered 'VISIT4'	System	30 Mar 2021 18:06:50

US3202179

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:53
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:20

US3202179

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered '30 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:20

US3202179
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered '13:00'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:20

US3202179
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User entered '30 Mar 2021 13:00'	System	30 Mar 2021 18:07:20

US3202179
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered '36.8' C	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:20

US3202179

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered 'Oral (Oral)'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:20

US3202179
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:53
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:20

US3202179
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:53
User entered '72'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:20

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User entered 'bpm'	System	30 Mar 2021 18:07:20

US3202179
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered '20'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:20

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User entered 'breaths/min'	System	30 Mar 2021 18:07:20

FDA-CBER-2022-1614-0447650

Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:53
User entered '149'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:20

US3202179
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User entered 'mmHg'	System	30 Mar 2021 18:07:20

US3202179

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered '85'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:20

US3202179
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User entered 'mmHg'	System	30 Mar 2021 18:07:20

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37

US3202179
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37

US3202179

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:27

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered '30 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:27

US3202179

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:53
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:37

US3202179

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered '30 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:37

US3202179

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered '13:05'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:37

US3202179

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User entered '30 Mar 2021 13:05'	System	30 Mar 2021 18:07:37

US3202179

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 18:07:40

US3202179
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:37
User entered '1'	System	30 Mar 2021 18:07:40

US3202179

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

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 19:36:12

US3202179

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

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 19:36:12

US3202179

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

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	01 Feb 2021 19:36:12

US3202179
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 19:36:12

US3202179

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:52

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 19:36:30

US3202179

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:52

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
User entered '0'	Teresa Deese (b) (4)	22 Apr 2021 16:38:41
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:46:46

US3202179

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:52

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 19:36:30

US3202179

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:52

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 18:47:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
Query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	22 Apr 2021 16:39:04
User entered 'Amendment 6 or later (Amendment 6 or later)'	Teresa Deese (b) (4)	22 Apr 2021 16:38:41
User opened query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 08:46:16
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:46:46

US3202179

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:52

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 19:36:30

US3202179

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:52

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	01 Feb 2021 19:36:30

US3202179

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:52

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
	(b) (4)	
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	01 Feb 2021 19:36:30

US3202179

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:52

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	01 Feb 2021 19:36:30

US3202179

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:52

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 19:36:30

US3202179

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:52

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered '1'	System	01 Feb 2021 19:36:30

US3202179

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:52

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered '1'	System	01 Feb 2021 19:36:30

US3202179

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:46:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered empty.	System	01 Feb 2021 19:37:35
DataPoint set to visible.	System	01 Feb 2021 19:36:30

US3202179

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:46:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered empty.	System	01 Feb 2021 19:37:35
DataPoint set to visible.	System	01 Feb 2021 19:36:30

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '13:03'	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered '1 Feb 2021 13:03'	System	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '36.9' C	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

FDA-CBER-2022-1614-0447693

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '94'	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'bpm'	System	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '16'	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'breaths/min'	System	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '149'	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'mmHg'	System	01 Feb 2021 19:37:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '94'	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'mmHg'	System	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 19:37:35

US3202179
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:46:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered empty.	System	01 Feb 2021 19:37:35
DataPoint set to visible.	System	01 Feb 2021 19:36:30

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '14:16'	Teresa Deese (b) (4)	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered '1 Feb 2021 14:16'	System	01 Feb 2021 19:38:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '36.5' C	Teresa Deese (b) (4)	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '84'	Teresa Deese (b) (4)	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'bpm'	System	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '16'	Teresa Deese (b) (4)	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'breaths/min'	System	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '142'	Teresa Deese (b) (4)	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'mmHg'	System	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '100'	Teresa Deese (b) (4)	01 Feb 2021 19:38:04

US3202179

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'mmHg'	System	01 Feb 2021 19:38:04

Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:46:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'No (N)'	Teresa Deese (b) (4)	01 Feb 2021 19:38:09

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 19:38:09

US3202179

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

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 19:38:23

US3202179

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

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 19:38:23

US3202179

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

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

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 18:56:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 19:38:23

US3202179

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

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'mRNA-1273'	System	01 Feb 2021 19:38:23
DataPoint set to visible.	System	01 Feb 2021 19:36:30

US3202179

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

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 19:38:23

US3202179

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

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '13:26'	Teresa Deese (b) (4)	01 Feb 2021 19:38:23

US3202179

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

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered '1 Feb 2021 13:26'	System	01 Feb 2021 19:38:23

US3202179

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

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Left Arm (LEFT ARM)'	Teresa Deese (b) (4)	01 Feb 2021 19:38:23

US3202179

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

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'ONCE'	System	01 Feb 2021 19:38:23

US3202179

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

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered 'INTRAMUSCULAR'	System	01 Feb 2021 19:38:23

US3202179

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 19:38:37

Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:46:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 19:38:37

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '13:23'	Teresa Deese (b) (4)	01 Feb 2021 19:38:37

US3202179

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered '1 Feb 2021 13:23'	System	01 Feb 2021 19:38:37

US3202179

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 19:38:47

US3202179

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '1 Feb 2021'	Teresa Deese (b) (4)	01 Feb 2021 19:38:47

US3202179

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '13:17'	Teresa Deese (b) (4)	01 Feb 2021 19:38:47

US3202179

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:52

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered '1 Feb 2021 13:17'	System	01 Feb 2021 19:38:47

US3202179

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

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Feb 2021 19:38:52

US3202179

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

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:07
User entered '1'	System	01 Feb 2021 19:38:52

US3202179
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 20:00:54

US3202179
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered '8 Feb 2021'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 20:00:54

US3202179

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 20:00:54

US3202179

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 20:00:54

US3202179
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:53
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 20:01:00

US3202179
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered '1'	System	19 Feb 2021 20:01:00

US3202179
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered '1'	System	19 Feb 2021 20:01:00
DataPoint set to visible.	System	19 Feb 2021 20:01:00

US3202179
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Mar 2021 19:45:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered '1 Mar 2021'	Teresa Deese (b) (4)	01 Mar 2021 19:45:52

US3202179
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52

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 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	01 Mar 2021 19:45:52

US3202179
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'OLD29'	System	01 Mar 2021 19:45:52

US3202179
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:46:52
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	01 Mar 2021 19:46:27

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Mar 2021 19:46:27

FDA-CBER-2022-1614-0447755

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '1 Mar 2021'	Teresa Deese (b) (4)	01 Mar 2021 19:46:27

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '13:56'	Teresa Deese (b) (4)	01 Mar 2021 19:46:27

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered '1 Mar 2021 13:56'	System	01 Mar 2021 19:46:27

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered '36.7' C	Teresa Deese (b) (4)	01 Mar 2021 19:46:27

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	01 Mar 2021 19:46:27

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Mar 2021 19:46:27

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '75'	Teresa Deese (b) (4)	01 Mar 2021 19:46:27

US3202179
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:46:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'bpm'	System	01 Mar 2021 19:46:27

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '16'	Teresa Deese (b) (4)	01 Mar 2021 19:46:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'breaths/min'	System	01 Mar 2021 19:46:27

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '151'	Teresa Deese (b) (4)	01 Mar 2021 19:46:27

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'mmHg'	System	01 Mar 2021 19:46:27

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '92'	Teresa Deese (b) (4)	01 Mar 2021 19:46:27

US3202179
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:46:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'mmHg'	System	01 Mar 2021 19:46:27

US3202179
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:46:52
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	01 Mar 2021 19:47:00

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Mar 2021 19:47:00

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '1 Mar 2021'	Teresa Deese (b) (4)	01 Mar 2021 19:47:00

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered '14:36'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:47:00

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered '1 Mar 2021 14:36'	System	01 Mar 2021 19:47:00

US3202179
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:46:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '36.4' C	Teresa Deese (b) (4)	01 Mar 2021 19:47:00

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	01 Mar 2021 19:47:00

US3202179
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:46:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Mar 2021 19:47:00

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered '76'	Teresa Deese (b) (4)	01 Mar 2021 19:47:00

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'bpm'	System	01 Mar 2021 19:47:00

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '16'	Teresa Deese (b) (4)	01 Mar 2021 19:47:00

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'breaths/min'	System	01 Mar 2021 19:47:00

US3202179
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '159'	Teresa Deese (b) (4)	01 Mar 2021 19:47:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'mmHg'	System	01 Mar 2021 19:47:00

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered '99'	Teresa Deese (b) (4)	01 Mar 2021 19:47:00

US3202179

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'mmHg'	System	01 Mar 2021 19:47:00

US3202179

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'No (N)'	Teresa Deese (b) (4)	01 Mar 2021 19:47:14

US3202179

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Teresa Deese (b) (4)	01 Mar 2021 19:47:14

US3202179

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Mar 2021 19:47:33

US3202179

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	01 Mar 2021 19:47:33

US3202179

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

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 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:47:33

US3202179
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:46:52

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'mRNA-1273'	System	01 Mar 2021 19:47:33
DataPoint set to visible.	System	19 Feb 2021 20:01:00

US3202179

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '1 Mar 2021'	Teresa Deese (b) (4)	01 Mar 2021 19:47:33

FDA-CBER-2022-1614-0447792

US3202179

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:52

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '14:03'	Teresa Deese (b) (4)	01 Mar 2021 19:47:33

FDA-CBER-2022-1614-0447793

US3202179
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:46:52

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered '1 Mar 2021 14:03'	System	01 Mar 2021 19:47:33

US3202179
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:46:52

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered 'Left Arm (LEFT ARM)'	Teresa Deese (b) (4)	01 Mar 2021 19:47:33

Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:46:52
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'ONCE'	System	01 Mar 2021 19:47:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 19:47:33

FDA-CBER-2022-1614-0447797

US3202179

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	01 Mar 2021 19:47:39

US3202179

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered '1'	System	01 Mar 2021 19:47:39

US3202179

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	08 Mar 2021 21:02:41

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '8 Mar 2021'	Lilian Nukuna (b) (4) (b) (4)	08 Mar 2021 21:02:41

FDA-CBER-2022-1614-0447801

US3202179

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	08 Mar 2021 21:02:41

FDA-CBER-2022-1614-0447802

US3202179
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:46:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	08 Mar 2021 21:02:41

US3202179

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	08 Mar 2021 21:02:52

US3202179
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:46:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:42
User entered '1'	System	08 Mar 2021 21:02:52

US3202179
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:33:09

US3202179
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '30 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 17:33:09

US3202179

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:52

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Clinic (Clinic)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:33:09

US3202179
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:46:52
Folder OID

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 17:33:09

US3202179

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 18:04:42

US3202179

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '30 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 18:04:42

US3202179

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '13:00'	Erica Osmundsen (b) (4)	30 Mar 2021 18:04:42

US3202179
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '30 Mar 2021 13:00'	System	30 Mar 2021 18:04:42

US3202179

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '36.8' C	Erica Osmundsen (b) (4)	30 Mar 2021 18:04:42

US3202179

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Oral (Oral)'	Erica Osmundsen (b) (4)	30 Mar 2021 18:04:42

US3202179
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 18:04:42

US3202179
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered '72'	Erica Osmundsen (b) (4)	30 Mar 2021 18:04:42

Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 18:04:42

US3202179

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '20'	Erica Osmundsen (b) (4)	30 Mar 2021 18:04:42

US3202179
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 18:04:42

US3202179

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '149'	Erica Osmundsen (b) (4)	30 Mar 2021 18:04:42

US3202179
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:04:42

US3202179

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '85'	Erica Osmundsen (b) (4)	30 Mar 2021 18:04:42

US3202179
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:46:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:04:42

US3202179

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 18:06:08

US3202179

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered '30 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 18:06:08

US3202179

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 18:06:19

US3202179

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Mar 2021 18:06:26
User entered '30 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	30 Mar 2021 18:06:26
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Mar 2021 18:06:19
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 18:06:19

US3202179

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered '13:05'	Erica Osmundsen (b) (4)	30 Mar 2021 18:06:19

US3202179

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:52

Collection date and time (derived)

Audit	User	Time (GMT)
User entered '30 Mar 2021 13:05'	System	30 Mar 2021 18:06:26
User entered empty.	System	30 Mar 2021 18:06:19

US3202179
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:46:52

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:08:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Oct 2020 18:36:15
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:58:46

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

AEID

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:34:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:06:29
User entered 'USA-US128-2021-mRNA-1273-P301000013'	System	31 Mar 2021 14:39:41
User entered 'New'	(b) (4), (b) (6)	31 Mar 2021 14:39:41

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
User closed query 'per hospital notes subject has history of CAD and previous stents x 3, please verify and update med history and verify AE term' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:07:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:07:51
Query 'per hospital notes subject has history of CAD and previous stents x 3, please verify and update med history and verify AE term' answered with 'CONFIRMED PER RECORDS AND PER SUBJECT, CAD WAS ONGOING AT START OF STUDY (3 STENTS IN 2019). MEDICAL HISTORY UPDATED AND THIS AE WILL BE UPDATED TO WORSENING OF CAD' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 18:47:05
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:45:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:45:53
Data point term sent to Coder	System	16 Apr 2021 18:45:22
Coding entries removed.	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
User entered 'WORSENING OF CORONARY ARTERY DISEASE' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
User opened query 'per hospital notes subject has history of CAD and previous stents x 3, please verify and update med history and verify AE term' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:43:40
Query 'per hospital records subject has a history of CAD with previous stents x 3. please verify' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:42:58

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Adverse event

Audit	User	Time (GMT)
User opened query 'per hospital records subject has a history of CAD with previous stents x 3. please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:40:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User closed query 'Please confirm hospital records requested x3 including D/C summary and medication records' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:21:25
Query 'Please confirm hospital records requested x3 including D/C summary and medication records' answered with 'CONFIRMED' (Site from CRA).	Erica Osmundsen (b) (4)	06 Apr 2021 21:11:07
User opened query 'Please confirm hospital records requested x3 including D/C summary and medication records' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 16:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:50
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 17:46:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 17:46:16
Data point term sent to Coder	System	30 Mar 2021 17:45:25
User entered 'CORONARY ARTERY DISEASE'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:51
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:53
User entered 'No (N)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:07:55
User entered 'No (N)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:57
User entered '19 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:59
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:17:20
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:08:01
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:17:23
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
User entered '22 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:08:02
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:04
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Severity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:08:09
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:08
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:08:11
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:08:13
User entered '1'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:15
User entered '19 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:47:58
User closed query 'D/c date = 24Mar2021, per D/C Summary, please verify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 13:47:45
User closed query 'PV Query: Please consider updating the hospital discharge date for the event, coronary artery disease as it was provided as 25 Mar 2021, which is not in accordance with discharge date for other events and medical records (24 Mar 2021). Please update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:59:59
Query 'D/c date = 24Mar2021, per D/C Summary, please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	19 Apr 2021 18:29:14
Query 'PV Query: Please consider updating the hospital discharge date for the event, coronary artery disease as it was provided as 25 Mar 2021, which is not in accordance with discharge date for other events and medical records (24 Mar 2021). Please update EDC accordingly.' answered with 'UPDATED' (Site from Safety).	Erica Osmundsen (b) (4)	19 Apr 2021 18:28:59
Signature has been broken.	Erica Osmundsen (b) (4)	19 Apr 2021 18:28:09
User entered '24 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Apr 2021 18:28:09
User opened query 'D/c date = 24Mar2021, per D/C Summary, please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:16:36
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:10:51
User opened query 'PV Query: Please consider updating the hospital discharge date for the event, coronary artery disease as it was provided as 25 Mar 2021, which is not in accordance with discharge date for other events and medical records (24 Mar 2021). Please update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:43:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:17

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '25 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:20
User entered 'No (N)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:08:21
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:08:24
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:08:25
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:08:27
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:08:30
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:31
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:40:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'PV Query: As the last dose of mRNA-1273 was given on 01 Mar 2021, please update the action taken with mRNA-1273 from none to not applicable. :' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 15:46:14
Query 'PV Query: As the last dose of mRNA-1273 was given on 01 Mar 2021, please update the action taken with mRNA-1273 from none to not applicable. :' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	09 Apr 2021 16:21:42
DataPoint Un-verified.	Teresa Deese (b) (4)	09 Apr 2021 16:21:21
Signature has been broken.	Teresa Deese (b) (4)	09 Apr 2021 16:21:21
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Teresa Deese (b) (4)	09 Apr 2021 16:21:21
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 01 Mar 2021, please update the action taken with mRNA-1273 from none to not applicable. :' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:36:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:37
User entered 'None (NONE)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52
None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
Signature has been broken.	Teresa Deese (b) (4)	13 Apr 2021 16:07:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:39
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:40:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:46
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:40
User entered '1'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

FDA-CBER-2022-1614-0447862

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:42
User entered '1'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:17:31
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:48
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
User closed query 'PV Query: Thanks for confirming appendicitis is acute and not chronic. Please consider adding "appendicitis" to medical history as a current ongoing condition as it was started before the SAE. If not so, please clarify.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:59:43
Query 'PV Query: Thanks for confirming appendicitis is acute and not chronic. Please consider adding "appendicitis" to medical history as a current ongoing condition as it was started before the SAE. If not so, please clarify.' answered with 'THE APPENDICITIS DID NOT START PRIOR TO SUBJECT'S ENROLLMENT IN THE STUDY, SO IT CANNOT BE LISTED AS MEDICAL HISTORY. THIS ACUTE CONDITION STARTED LONG AFTER SUBJECT HAD ENTERED STUDY, THUS IT IS AN AE AS WELL. ' (Site from Safety).	Erica Osmundsen (b) (4)	19 Apr 2021 18:28:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:11:11
User opened query 'PV Query: Thanks for confirming appendicitis is acute and not chronic. Please consider adding "appendicitis" to medical history as a current ongoing condition as it was started before the SAE. If not so, please clarify.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:44:23
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Narrative

Audit	User	Time (GMT)
User entered 'SUBJECT FOUND TO HAVE CAD UPON CARDIAC WORKUP FOR APPENDECTOMY AND WAS ADMITTED FOR CARDIAC CATHETERIZATION AND STENTING. POOR HISTORIAN--NUMBER OF STENTS OR OTHER DETAILS NOT YET KNOWN BUT MED RECORDS REQUESTED. SUBJECT UNDERWENT CARDIAC CATHETERIZATION AND WAS FOUND TO HAVE 90% STENOSIS IN LAD, STENT PLACED, RECORDS REDACTED AND EMAILED TO SAFETY\ UPDATED INFORMATION: SUBJECT'S MEDICAL RECORDS AND CALLS WITH SUBJECT CLARIFYING RECORDS REVEALED THAT SUBJECT HAD A HISTORY OF CAD UPON ENTERING THE STUDY AND HAD 3 CARDIAC STENTS IN 2019. THIS AE TERM WAS UPDATED TO "WORSENING" AND CAD WAS ADDED TO MEDICAL HISTORY' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 18:45:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:40:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'PV Query: -Please provide the subject's medical history. -Please confirm if both atrial fibrillation and appendicitis should be under medical history for the subject. If yes, please update the SAE form and re submit the SAE form.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 13:21:20
User closed query 'PV Query: Please consider adding "atrial fibrillation" to medical history in eCRF with a start date.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 13:21:16
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).' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 13:21:04
User closed query 'PV Query: Please provide more details about the appendectomy.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 13:21:01

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 13:20:58
User closed query 'PV Query: Please consider adding "appendicitis" to medical history in eCRF with a start date (and an end date if it is not an ongoing event).' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 13:20:23
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 13:20:12
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 13:19:59
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)	14 Apr 2021 13:19:56
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'RECORDS RECEIVED AND D/C SUMMARY WITH CARDIAC PROCEDURAL NOTES REDACTED AND SUBMITTED TO SAFETY VIA EMAIL' (Site from Safety).	Erica Osmundsen (b) (4)	13 Apr 2021 21:27:09
DataPoint Un-verified.	Erica Osmundsen (b) (4)	13 Apr 2021 21:26:42

FDA-CBER-2022-1614-0447868

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Narrative

Audit	User		Time (GMT)
Signature has been broken.	Erica Osmundsen	(b) (4)	13 Apr 2021 21:26:42
User entered 'SUBJECT FOUND TO HAVE CAD UPON CARDIAC WORKUP FOR APPENDECTOMY AND WAS ADMITTED FOR CARDIAC CATHETERIZATION AND STENTING. POOR HISTORIAN--NUMBER OF STENTS OR OTHER DETAILS NOT YET KNOWN BUT MED RECORDS REQUESTED. SUBJECT UNDERWENT CARDIAC CATHETERIZATION AND WAS FOUND TO HAVE 90% STENOSIS IN LAD, STENT PLACED, RECORDS REDACTED AND EMAILED TO SAFETY' reason for change: Data Entry Error	Erica Osmundsen	(b) (4)	13 Apr 2021 21:26:42
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'RECORDS SENT VIA EMAIL JUST NOW' (Site from Safety).	Erica Osmundsen	(b) (4)	13 Apr 2021 21:23:31
Query 'PV Query: -Please provide the subject's medical history. -Please confirm if both atrial fibrillation and appendicitis should be under medical history for the subject. If yes, please update the SAE form and re submit the SAE form.' answered with 'at fib inactivated in AE & put in med Hx w unk start date. appendicitis is acute not chronic so AE' (Site from Safety).	Teresa Deese	(b) (4)	13 Apr 2021 16:08:07
Query 'PV Query: Please consider adding "atrial fibrillation" to medical history in eCRF with a start date.' answered with 'done' (Site from Safety).	Teresa Deese	(b) (4)	13 Apr 2021 16:06:06
Query 'PV Query: Please consider adding "appendicitis" to medical history in eCRF with a start date (and an end date if it is not an ongoing event).' answered with 'add to med hx when start date was after beginning of study?' (Site from Safety).	Teresa Deese	(b) (4)	13 Apr 2021 16:04:37

FDA-CBER-2022-1614-0447869

Audit	User	Time (GMT)
Query 'PV Query: Please provide more details about the appendectomy.' answered with 'did not have surgery. responded to conservative Tx w abx so no surgery.' (Site from Safety).	Teresa Deese (b) (4)	13 Apr 2021 16:03:51
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).' answered with 'abx for appendicitis- conservative Tx. PTCA/stent for CAD along w Rx. Rx list updated' (Site from Safety).	Teresa Deese (b) (4)	13 Apr 2021 16:03:20
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'med Hx updated from hospital records. COPD, HTN, age, male, no exercise' (Site from Safety).	Teresa Deese (b) (4)	13 Apr 2021 16:02:11
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 'no covid testing noted' (Site from Safety).	Teresa Deese (b) (4)	13 Apr 2021 15:59:25
User opened query 'PV Query: -Please provide the subject's medical history. -Please confirm if both atrial fibrillation and appendicitis should be under medical history for the subject. If yes, please update the SAE form and re submit the SAE form.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:39:54
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:38:43
User opened query 'PV Query: Please consider adding "appendicitis" to medical history in eCRF with a start date (and an end date if it is not an ongoing event).' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:38:01

FDA-CBER-2022-1614-0447870

US3202179
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:46:52
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider adding "atrial fibrillation" to medical history in eCRF with a start date.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:37:41
User opened query 'PV Query: Please provide more details about the appendectomy.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:36:23
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).' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:36:04
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:35:45
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:35:25
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)	09 Apr 2021 15:34:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:08:49
User entered 'SUBJECT FOUND TO HAVE CAD UPON CARDIAC WORKUP FOR APPENDECTOMY AND WAS ADMITTED FOR CARDIAC CATHETERIZATION AND STENTING. POOR HISTORIAN--NUMBER OF STENTS OR OTHER DETAILS NOT YET KNOWN BUT MED RECORDS REQUESTED'	Erica Osmundsen (b) (4)	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 17:44:34

US3202179

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:52

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 17:44:34

US3202179
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:46:52

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:09:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 17:55:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 17:55:02
Data point term sent to Coder	System	30 Mar 2021 17:53:34
User entered 'appendicitis'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:09:29
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:46:52
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:31
User entered 'No (N)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:09:32
User entered 'No (N)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:34
User entered '19 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:38
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:52:34

US3202179
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:46:52
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:39
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:46:52
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:09:41
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:43
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:52:34

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:49:32
User closed query 'source = grade 2, Moderate, please verify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 13:49:16
Query 'source = grade 2, Moderate, please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	19 Apr 2021 18:27:23
Signature has been broken.	Erica Osmundsen (b) (4)	19 Apr 2021 18:26:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Apr 2021 18:26:58
User opened query 'source = grade 2, Moderate, please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:18:41
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:18:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

FDA-CBER-2022-1614-0447886

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Is the adverse event serious?

Audit	User	Time (GMT)
User closed query 'Per MM: please confirm seriousness assessment. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 04:57:27
Query 'Per MM: please confirm seriousness assessment. ' answered with 'subject not hospitalized for appendicitis and it was managed with antibiotics' (Site from DM).	Erica Osmundsen (b) (4)	26 Apr 2021 12:22:45
User opened query 'Per MM: please confirm seriousness assessment. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:02:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:18:03
User closed query 'please verify as subject was admitted to hospital for management and antibiotics.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:18:01
Query 'please verify as subject was admitted to hospital for management and antibiotics.' answered with 'CONFIRMED--SUBJECT PRESENTED AT ER FOR ABDOMINAL PAIN AND WAS BEING WORKED UP FOR POSSIBLE APPENDECTOMY WHEN CARDIAC ISSUES FOUND. ABDOMINAL PAIN RESOLVED THE FOLLOWING DAY AND NO SURGERY PLANNED FOR APPENDIX AT THIS TIME (TREATED CONSERVATIVELY ONLY) NO ACTUAL HOSPITAL ADMISSION FOR APPENDICITIS (ONLY ER VISIT ORIGINALLY STARTED FOR THIS INDICATION)' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 18:54:21
User opened query 'please verify as subject was admitted to hospital for management and antibiotics.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:53:07
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 14:52:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:47
User entered 'No (N)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:50
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:51
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:53
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:09:54
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:58
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:10:01
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:46:52

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:10:03
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:10:05
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:10:06
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:10:09
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:10:10
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:10:12
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:46:52
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:10:14
User entered 'None (NONE)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:10:19
User entered '1'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:10:20
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

FDA-CBER-2022-1614-0447902

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:10:22
User entered '0'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:10:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:10:25
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:10:27
User entered 'subject planning to have appendectomy in April 2021 but was unable to undergo that procedure due to failed cardiac workup prior to appendectomy'	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 17:52:34

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

AEID

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:00:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:54:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'USA-US128-2021-mRNA-1273-P301000013'	(b) (4), (b) (6)	14 Apr 2021 13:16:22

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular tachycardia, LLT: Wide complex ventricular tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:29:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:29:54
Data point term sent to Coder	System	13 Apr 2021 16:17:51
User entered 'wide complex ventricular tachycardia'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:46:52
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:46:52

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:46:52

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '20 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:17:18

US3202179
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

FDA-CBER-2022-1614-0447917

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '21 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	13 Apr 2021 16:17:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:17:32
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	13 Apr 2021 16:17:18
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:25
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered '1'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '19 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:46:52
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:46:52
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:55:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:56:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '1'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:56:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:56:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:46:52
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:56:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
User closed query 'PV Query: Thanks for confirming appendicitis is acute and not chronic. Please consider adding "appendicitis" to medical history as a current ongoing condition as it was started before the SAE. If not so, please clarify.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 19:00:39
Query 'PV Query: Thanks for confirming appendicitis is acute and not chronic. Please consider adding "appendicitis" to medical history as a current ongoing condition as it was started before the SAE. If not so, please clarify.' answered with 'THE APPENDICITIS DID NOT START PRIOR TO SUBJECT'S ENROLLMENT IN THE STUDY, SO IT CANNOT BE LISTED AS MEDICAL HISTORY. THIS ACUTE CONDITION STARTED LONG AFTER SUBJECT HAD ENTERED STUDY, THUS IT IS AN AE AS WELL. ' (Site from Safety).	Erica Osmundsen (b) (4)	19 Apr 2021 18:25:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:19:37
User closed query 'please complete' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:19:30
User opened query 'PV Query: Thanks for confirming appendicitis is acute and not chronic. Please consider adding "appendicitis" to medical history as a current ongoing condition as it was started before the SAE. If not so, please clarify.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:43:06
Query 'please complete' answered with 'done' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 19:13:14

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Narrative

Audit	User	Time (GMT)
User entered 'SUBJECT HAS HISTORY OF CHRONIC AFIB AND WAS SEEN BY CARDIOLOGY ON 20/MAR/21 FOR CARDIAC CLEARANCE FOR APPENDECTOMY SURGERY. THE CARDIOLOGIST NOTED THAT HE WAS HAVING WIDE COMPLEX TACHYCARDIA EPISODES SO AN ISCHEMIC WORKUP WAS PLANNED WITH NUCLEAR STRESS TEST PRIOR TO APPROVAL OF APPENDECTOMY. HOWEVER, THE STESS TEST WAS CANCELLED DUE TO TO RECURRENCE OF ARRHYTHMIAS AND SUBJECT WAS SENT TO MAIN HOSPITAL FOR CARDIAC CATHETERIZATION AND FURTHER EVAL.' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 19:07:40
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 19:07:24
User entered 'SUBJECT HAS HISTORY OF CHRONIC AFib and was seen by cardiology on 20/MAR/21 for cardiac clearance for appendectomy surgery. The cardiologist noted that he was having wide complex tachycardia episodes so an Ischemic workup was planned with nuclear stress test prior to approval of appendectomy. However, the stess test was cancelled due to to recurrence of arrhythmias and subject was sent to main hospital for cardiac catheterization and furether eval.' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 19:07:24
User opened query 'please complete' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:56:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:17:32
User entered '0'	System	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:46:52

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 16:17:18

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

AEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:51:29
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:06:25
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 19:03:50
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:03:50
User entered empty; reason for change New Information	(b) (4), (b) (6)	19 Apr 2021 19:03:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'USA-US128-2021-mRNA-1273-P301000013'	(b) (4), (b) (6)	14 Apr 2021 13:16:42

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Lumbar vertebral fracture, LLT: Lumbar vertebral fracture L4 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 11:14:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 11:14:24
Data point term sent to Coder	System	13 Apr 2021 16:20:55
User entered 'L4 vertebral compression Fx'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '19 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:19:58

US3202179
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:41
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:19:58

US3202179
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:46:52
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:46:52
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:50:32
User closed query 'please verify as this was an incidental finding ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 13:50:20
Query 'please verify as this was an incidental finding ' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:32
Signature has been broken.	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:13
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:13
User opened query 'please verify as this was an incidental finding ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:21:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	13 Apr 2021 16:20:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:20:24
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	13 Apr 2021 16:20:09
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:20:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:51:55
User closed query 'please verify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 13:51:41
Query 'please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:46
Signature has been broken.	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:13
User entered '0' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:13
User opened query 'please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:21:38
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	13 Apr 2021 16:20:09
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	13 Apr 2021 16:20:09
User entered '1' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:20:09
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	13 Apr 2021 16:19:58
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:46:52

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:54:20
Signature has been broken.	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:13
User entered empty; reason for change Data Entry Error	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '19 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

FDA-CBER-2022-1614-0447963

US3202179
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:46:52

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:54:45
Signature has been broken.	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:13
User entered empty; reason for change Data Entry Error	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:53:39
Signature has been broken.	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:13
User entered empty; reason for change Data Entry Error	Erica Osmundsen (b) (4)	19 Apr 2021 18:23:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:52:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:52:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:52:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:52:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:21:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:21:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:21:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:21:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:21:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '1'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:23:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:23:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:23:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:23:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'incidental finding. subj admitted for appendicitis, had cardiac w/u w stent. Fx found on x-ray'	Teresa Deese (b) (4)	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 18:23:13
User entered '1'	System	13 Apr 2021 16:20:24
User entered '0'	System	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:46:52

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 16:19:58

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

AEID

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:05:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'USA-US128-2021-mRNA-1273-P301000013'	(b) (4), (b) (6)	14 Apr 2021 13:17:06

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute coronary syndrome, LLT: Acute coronary syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 06:48:04
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 06:48:04
Data point term sent to Coder	System	13 Apr 2021 16:24:07
User entered 'acute coronary syndrome >24 hrs duration'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:32
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:46:52

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '19 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:46:52

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:23:39

US3202179
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:29
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:23:39

US3202179
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:46:52
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:46:52
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '1'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:46:52

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:46:46
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:46:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '19 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:45:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:46:52
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '1'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '1'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:46:52
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:23:27
User closed query 'please complete details' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:23:25
Query 'please complete details' answered with 'done' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 19:35:04
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 19:30:51
User entered 'in medical records related to worsening of CAD and stent placement, subject is noted as having acute coronary syndrome of >24 hours duration but no history of cardiac arrest or MI' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 19:30:51
User opened query 'please complete details' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:48:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:23:39

US3202179

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:46:52

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 16:23:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:58:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:46:17

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:06:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
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)	24 Sep 2020 21:47:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:47:54
Data point term sent to Coder	System	24 Sep 2020 21:47:20
User entered 'Tylenol'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:06:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:07:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Migraines'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:07:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '1000'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:07:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:07:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:08:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'as needed (PRN)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:08:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:08:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:08:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:09:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'UN UNK 2000'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:09:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:10:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:10:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:10:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:47:03

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:47:03

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:11:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 18:04:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 18:04:09
Data point term sent to Coder	System	30 Mar 2021 18:02:45
Coding entries removed.	Erica Osmundsen (b) (4)	30 Mar 2021 18:02:38
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:38:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:38:03
Data point term sent to Coder	System	26 Oct 2020 18:40:03
User entered 'Eliquis'	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:11:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	30 Mar 2021 18:02:38
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:12:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'ATRIAL FIBRILLATION' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	30 Mar 2021 18:02:38
User entered 'prevent stroke due to clots in at fib'	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:12:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '5'	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:12:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

FDA-CBER-2022-1614-0448041

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:13:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:13:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:13:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:14:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:14:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:14:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'UN Sep 2020'	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:14:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:15:14
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:15:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 18:39:10

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:16:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:38:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:38:39
Data point term sent to Coder	System	26 Oct 2020 18:41:13
User entered 'flu shot'	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:16:38
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 09:59:52
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	01 Feb 2021 19:35:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	01 Feb 2021 19:35:46
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 06:43:45
User entered 'No (N)'	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'prevent flu'	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:17:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0.5'	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:21:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mL (mL)'	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:21:42
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:22:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated, and given the Start and Stop Dates of the medication. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 09:59:55
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated, and given the Start and Stop Dates of the medication. Please update the Frequency as appropriate.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	01 Feb 2021 19:35:59
User entered 'once (ONCE)' reason for change: Data Entry Error	Teresa Deese (b) (4)	01 Feb 2021 19:35:40
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated, and given the Start and Stop Dates of the medication. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 06:44:05
User entered 'once daily (QD)'	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:22:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:22:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'Intramuscular (INTRAMUSCULAR)'	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:22:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:23:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '9 Oct 2020'	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:23:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	26 Oct 2020 18:42:06
User entered '9 Oct 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	26 Oct 2020 18:42:06
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	26 Oct 2020 18:41:05
User entered empty.	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:23:58
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
User entered empty.	System	01 Feb 2021 19:35:40
User entered '1'	System	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
User entered empty.	System	01 Feb 2021 19:35:40
User entered '1'	System	26 Oct 2020 18:41:05

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:11
User entered empty.	System	01 Feb 2021 19:35:40
User entered '804 (804)'	System	26 Oct 2020 18:41:05

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:01:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 06:57:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 06:57:42
Data point term sent to Coder	System	13 Apr 2021 16:41:30
User entered 'ASA'	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:01:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:01:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'coronary artery disease'	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:01:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '81'	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:01:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:01:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:01:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'once daily (QD)'	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:02:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:40:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:51:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:51:32
Data point term sent to Coder	System	13 Apr 2021 16:41:34
User entered 'plavix'	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'CAD stent placement'	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '75'	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:42
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'once daily (QD)'	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:48
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:04:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:41:29

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:41:29

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:42:54
Data point term sent to Coder	System	13 Apr 2021 16:43:35
User entered 'metoprolol'	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'CAD arrhythmias- at fib wide-complex ventricular tachycardia'	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered '50'	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:05:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:58:23
DataPoint Un-verified.	Erica Osmundsen (b) (4)	19 Apr 2021 18:40:44
Signature has been broken.	Erica Osmundsen (b) (4)	19 Apr 2021 18:40:44
User entered '24 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Apr 2021 18:40:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:00
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:58:47
User closed query 'source = 22Mar2021' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 13:58:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Apr 2021 18:40:44
Query 'source = 22Mar2021' answered with 'updated' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 19:37:17
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 19:37:13
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 19:37:13
User opened query 'source = 22Mar2021' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:08:22
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:04
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4) (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:59:27
User entered empty; reason for change Data Entry Error	Erica Osmundsen (b) (4)	19 Apr 2021 18:40:44
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 19:37:13
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 19:37:13
User entered '22 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 19:37:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:06:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:42:37

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:52:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:52:29
Data point term sent to Coder	System	13 Apr 2021 16:43:35
User entered 'ATORVASTATIN' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:43:21
User entered 'atorvastating'	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'CAD'	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '20'	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:46:52
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'once daily (QD)'	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:46:52
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:40
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:43:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:43:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:12:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:22:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:22:52
Data point term sent to Coder	System	13 Apr 2021 16:44:36
User entered 'midolazam'	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:12:35
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:12:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'procedure sedation for CAD stent'	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:12:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0.5'	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:12:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:12:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'once (ONCE)'	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
User entered empty.	System	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
User entered empty.	System	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:01
User entered empty.	System	13 Apr 2021 16:44:25

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:31:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:31:32
Data point term sent to Coder	System	13 Apr 2021 16:45:38
User entered 'fentanyl'	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'procedure sedation for CAD stent'	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '25'	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'ug (ug)'	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'once (ONCE)'	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:41
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:43
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	13 Apr 2021 16:45:24
User entered '22 Mar 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:45:24
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	13 Apr 2021 16:45:15
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:45:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
User entered empty.	System	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
User entered empty.	System	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:07
User entered empty.	System	13 Apr 2021 16:45:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:10:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:10:55
Data point term sent to Coder	System	13 Apr 2021 16:46:38
User entered 'diphenhydramine'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'prophylaxis'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '25'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'once (ONCE)'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:20
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
User entered empty.	System	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
User entered empty.	System	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:15
User entered empty.	System	13 Apr 2021 16:46:09

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:53:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:53:15
Data point term sent to Coder	System	13 Apr 2021 16:47:39
User entered 'furosemide'	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'CHF'	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:56:22
User closed query 'D/C summary = 40, please verify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 13:56:10
Query 'D/C summary = 40, please verify' answered with 'corrected' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 19:36:34
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 19:36:28
User entered '40' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 19:36:28
User opened query 'D/C summary = 40, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:15:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '20'	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'once daily (QD)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:47:16

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
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)	14 Apr 2021 10:47:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:47:50
Data point term sent to Coder	System	13 Apr 2021 16:48:40
User entered 'gabapentin'	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'L4 vertebral compression Fx'	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '300'	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'three times daily (TID)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:47:56

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:53:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:53:20
Data point term sent to Coder	System	13 Apr 2021 16:48:40
User entered 'multivitamin'	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'supplement'	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '1'	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'tablet (TABLET)'	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'once daily (QD)'	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:48:35

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:20:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:20:41
Data point term sent to Coder	System	13 Apr 2021 16:50:41
User entered 'amoxil/clavulanate'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'appendicitis'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '875/125'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

FDA-CBER-2022-1614-0448256

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:50:07
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	13 Apr 2021 16:50:07
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	13 Apr 2021 16:50:00
User entered '1 Apr 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:50:00

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:53:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:53:38
Data point term sent to Coder	System	13 Apr 2021 16:51:42
User entered 'zosyn'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'appendicitis'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '3.375'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'g (g)'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

FDA-CBER-2022-1614-0448275

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'four times daily (QID)'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '19 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
User entered '4'	System	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
User entered '1'	System	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:28
User entered '804 (804)'	System	13 Apr 2021 16:51:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:54:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:54:42
Data point term sent to Coder	System	13 Apr 2021 16:53:43
User entered 'heparin drip'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'acute coronary syndrome'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '6'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Other (OTHER)'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'IV drip rate variable based on PTT readings & sliding scale'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'other (OTHER)'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'continuous drip'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '21 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:32
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
User entered empty.	System	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
User entered empty.	System	13 Apr 2021 16:52:58

FDA-CBER-2022-1614-0448305

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:35
User entered empty.	System	13 Apr 2021 16:52:58

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE, PRODUCTSYNONYM: LOPRESSOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:51:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:51:00
Data point term sent to Coder	System	13 Apr 2021 16:54:47
User entered 'lopressor (metoprolol)'	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:23:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:11
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'prophylaxis'	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '15'	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:36
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'once (ONCE)'	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

FDA-CBER-2022-1614-0448313

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	13 Apr 2021 16:54:24
User entered '22 Mar 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 16:54:24
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	13 Apr 2021 16:54:15
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
User entered empty.	System	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
User entered empty.	System	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:42
User entered empty.	System	13 Apr 2021 16:54:15

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:08:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:08:44
Data point term sent to Coder	System	13 Apr 2021 16:55:49
User entered 'carvedilol'	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'CAD CHF'	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '25'	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '22 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:55:08

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:55:08

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
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: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:54:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:54:56
Data point term sent to Coder	System	13 Apr 2021 16:56:50
User entered 'hydrocodone/acetaminophen'	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'L4 compression Fx'	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '7.5/300'	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:22
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 16:55:55

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
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)	14 Apr 2021 13:46:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:46:00
Data point term sent to Coder	System	13 Apr 2021 16:56:50
User entered 'methacarbamol'	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'L4 compression Fx'	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '750'	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'three times daily (TID)'	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:56:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:56:39

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:55:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:55:00
Data point term sent to Coder	System	13 Apr 2021 16:57:51
User entered 'miralax'	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'prophylaxis'	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '17'	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'g (g)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

FDA-CBER-2022-1614-0448383

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'once daily (QD)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:45
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:57:14

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:55:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:55:00
Data point term sent to Coder	System	13 Apr 2021 16:57:51
User entered 'docusate'	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'prophylaxis'	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '100'	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mg (mg)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:39
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:57:46

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE, PRODUCTSYNONYM: KCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:54:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:54:52
Data point term sent to Coder	System	13 Apr 2021 16:58:51
User entered 'KCl'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'prophylaxis'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '10'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Other (OTHER)'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:29:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'mEq'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:29:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:29:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:29:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:29:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:29:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '24 Mar 2021'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:29:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:29:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:29:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:29:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:46:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 16:58:38

US3202179

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:46:52

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:25:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	30 Mar 2021 17:52:42
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 21:58:53

US3202179

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:52

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:13:18
User entered '22 Mar 2021'	Erica Osmundsen (b) (4)	30 Mar 2021 17:53:07

US3202179

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:52

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:13:18
User entered 'CARDIAC STENT PLACEMENT'	Erica Osmundsen (b) (4)	30 Mar 2021 17:53:07

US3202179

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:52

Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:13:18
User entered 'Adverse Event (AE)'	Erica Osmundsen (b) (4)	30 Mar 2021 17:53:07

US3202179

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:52

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:13:18
User entered empty.	Erica Osmundsen (b) (4)	30 Mar 2021 17:53:07

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:53
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:49
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'USA-US128-2021-MRNA-1273-P301000013'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Mark'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'McKenzie'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'US'	System	31 Mar 2021 14:40:06

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 13:18:27
User entered '4'	System	19 Apr 2021 19:07:31
User entered '3'	System	14 Apr 2021 13:19:26
User entered '2'	System	12 Apr 2021 15:49:35
User entered '1'	System	31 Mar 2021 14:40:06

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:53
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'USA-US128-2021-MRNA-1273-P301000013'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

FDA-CBER-2022-1614-0448452

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

FDA-CBER-2022-1614-0448455

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Mark'	System	31 Mar 2021 14:39:41

FDA-CBER-2022-1614-0448458

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'McKenzie'	System	31 Mar 2021 14:39:41

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'US'	System	31 Mar 2021 14:40:06

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 13:18:27
User entered '4'	System	19 Apr 2021 19:07:31
User entered '3'	System	14 Apr 2021 13:19:26
User entered '2'	System	12 Apr 2021 15:49:35
User entered '1'	System	31 Mar 2021 14:40:06

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:46:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
User entered '31/Mar/2021 09:40'	(b) (4) System	31 Mar 2021 14:40:06

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:46:52

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)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered '1'	(b) (4), (b) (6)	31 Mar 2021 14:40:06

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:53
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'USA-US128-2021-MRNA-1273-P301000013'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

FDA-CBER-2022-1614-0448466

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

FDA-CBER-2022-1614-0448470

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Mark'	System	31 Mar 2021 14:39:41

FDA-CBER-2022-1614-0448472

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'McKenzie'	System	31 Mar 2021 14:39:41

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:52

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'US'	System	31 Mar 2021 14:40:06

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 13:18:27
User entered '4'	System	19 Apr 2021 19:07:31
User entered '3'	System	14 Apr 2021 13:19:26
User entered '2'	System	12 Apr 2021 15:49:35
User entered '1'	System	31 Mar 2021 14:40:06

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:46:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 18:09:31
User entered '12/Apr/2021 11:49'	(b) (4) System	12 Apr 2021 15:49:35

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:46:52

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)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:09:31
User entered '1'	(b) (4), (b) (6)	12 Apr 2021 15:49:35

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:52

SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:53
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'USA-US128-2021-MRNA-1273-P301000013'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

FDA-CBER-2022-1614-0448483

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

FDA-CBER-2022-1614-0448484

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Mark'	System	31 Mar 2021 14:39:41

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'McKenzie'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'US'	System	31 Mar 2021 14:40:06

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 13:18:27
User entered '4'	System	19 Apr 2021 19:07:31
User entered '3'	System	14 Apr 2021 13:19:26
User entered '2'	System	12 Apr 2021 15:49:35
User entered '1'	System	31 Mar 2021 14:40:06

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:46:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:19:56
User entered '14/Apr/2021 09:19'	System	14 Apr 2021 13:19:26

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:46:52

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)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:56
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:19:26

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:53
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'USA-US128-2021-MRNA-1273-P301000013'	System	31 Mar 2021 14:39:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

FDA-CBER-2022-1614-0448493

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

FDA-CBER-2022-1614-0448496

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Mark'	System	31 Mar 2021 14:39:41

FDA-CBER-2022-1614-0448500

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'McKenzie'	System	31 Mar 2021 14:39:41

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:52

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'US'	System	31 Mar 2021 14:40:06

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 13:18:27
User entered '4'	System	19 Apr 2021 19:07:31
User entered '3'	System	14 Apr 2021 13:19:26
User entered '2'	System	12 Apr 2021 15:49:35
User entered '1'	System	31 Mar 2021 14:40:06

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:46:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:24:56
User entered '19/Apr/2021 15:07'	System	19 Apr 2021 19:07:31

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:46:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:24:56
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 19:07:31

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:53
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:46:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'USA-US128-2021-MRNA-1273-P301000013'	System	31 Mar 2021 14:39:41

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Yes (Y)'	System	31 Mar 2021 14:39:41

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'No (N)'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'Mark'	System	31 Mar 2021 14:39:41

US3202179
Folder: SAE USA-US128-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 15:46:52

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'McKenzie'	System	31 Mar 2021 14:39:41

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:25:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:42:06
User entered 'US'	System	31 Mar 2021 14:40:06

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 13:18:27
User entered '4'	System	19 Apr 2021 19:07:31
User entered '3'	System	14 Apr 2021 13:19:26
User entered '2'	System	12 Apr 2021 15:49:35
User entered '1'	System	31 Mar 2021 14:40:06

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:46:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:24:56
User entered '20/Apr/2021 06:18'	System	20 Apr 2021 13:18:27

US3202179

Folder: SAE USA-US128-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:46:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:24:56
User entered '1'	(b) (4), (b) (6)	20 Apr 2021 13:18:27