US3192291 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

US3192291
Form: Participant Creation
Data signed: (b) (4) **03 Apr 2021 23:48:56**
Generated On: 09 Jun 2021 15:40:16

Participant ID   US3192291

mRNA-1273-P301 Completion Guidelines

US3192291

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	16 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	SCRN

US3192291

Folder: Screening

Form: Demographics

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female ⬤
	Male ◯
Ethnicity	Hispanic or Latino ◯
	Not Hispanic or Latino ⬤
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)

White	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

US3192291

Folder: Screening

Form: Enrollment

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Date of Informed Consent *(dd MMM yyyy)*	16 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

US3192291

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Did the participant meet all eligibility criteria?   Yes ●

    No ○

Were any significant conditions reported?   Yes ⬤

                                                             No ◯

US3192291

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3192291

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Condition	OBSESSIVE COMPULSIVE DISORDER
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Condition	BIPOLAR II
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3192291

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Condition	URINARY TRACT INFECTION
Start date (dd MMM yyyy)	UN AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3192291

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Condition	APPENDECTOMY
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	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3192291

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Condition	BENIGN BREAST LESION
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	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3192291

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0407412

US3192291

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **14 Feb 2021 02:36:56**
Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	16 AUG 2020
Time of assessment *(00:00-23:59)*	11:20 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 11:20
Height *(xxx.x)*	64.5 in
Weight *(xxx.x)*	183.2 lb
BMI *(xxx.x)*	31.02530 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-2022-1614-0407414

US3192291

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?   Yes ⬤

                                                                                                        No ◯

Date of examination *(dd MMM yyyy)*   16 AUG 2020

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

US3192291

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Date of assessment *(dd MMM yyyy)*	16 AUG 2020

Is the participant of childbearing potential?

Yes ○
No ⬤

If No, what is the reason?

Surgically sterile ○
Post-menopausal ⬤
Partner medically sterile ○
Not reached age of Menarche ○
Other ○

If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	UN UNK 1995
Date of last menstruation unknown	False

US3192291

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Was the pregnancy test performed?	Yes ⬤
	No ◯
Date of test *(dd MMM yyyy)*	16 AUG 2020
Test performed	Urine ⬤
	Serum ◯
Result	Positive ◯
	Negative ⬤
Was FSH sample collected?	Yes ◯
	No ⬤
Collection date	
Collection time	
Collection date and time (derived)	

US3192291
Folder: Screening
Form: Risk of Exposure
Data signed: ▨ (b) (4) ▨ 14 Feb 2021 02:36:56
Generated On: 09 Jun 2021 15:40:16

Occupational Risk

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

Specify _____

Location and Living Circumstances Risk (check all that apply)

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

US3192291
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **14 Feb 2021 02:36:56**
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: Visit 1 Day 1

Form: Visit Date

Data signed:　(b) (4)　**14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	16 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

US3192291

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

What was the date of randomization? *(dd MMM yyyy)*	16 AUG 2020
What was the participant's randomization number?	186548

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

US3192291
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **14 Feb 2021 02:36:56**
Generated On: 09 Jun 2021 15:40:16

Height	ND - Not Done
Weight	ND - Not Done

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

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)*	16 AUG 2020
Time of assessment *(00:00-23:59)*	09:45 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 09:45
Temperature *(xxx.x)*	97.4 F
Route of measurement	Oral ◯
	Axillary ◯
	Other ⬤
If Other, specify	TEMPORAL
Pulse *(xxx)*	62 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

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)*	16 AUG 2020
Time of assessment *(00:00-23:59)*	11:00 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 11:00
Temperature *(xxx.x)*	96.9 F
Route of measurement	Oral ◯
	Axillary ◯
	Other ⬤
If Other, specify	TEMPORAL
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	95 mmHg
Diastolic Blood Pressure units	MMHG

US3192291

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

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.

US3192291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Was the pregnancy test performed?	Yes ⭕
	No ⬤

Date of test *(dd MMM yyyy)* _____

Test performed	Urine ⭕
	Serum ⭕

Result	Positive ⭕
	Negative ⭕

Was FSH sample collected?	Yes ⭕
	No ⭕

Collection date _____

Collection time _____

Collection date and time (derived) _____

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)*	16 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:20 (24 HR)
Treatment Date and Time (derived)	16 AUG 2020 10:20

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) **14 Feb 2021 02:36:56**
Generated On: 09 Jun 2021 15:40:16

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	16 AUG 2020
Collection time *(00:00-23:59)*	10:04 (24 HR)
Collection date and time (derived)	16 AUG 2020 10:04

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Collection date *(dd MMM yyyy)*			16 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:09	16 AUG 2020 10:09
Nasopharyngeal Swab 2	No		

US3192291
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **14 Feb 2021 02:36:56**
Generated On: 09 Jun 2021 15:40:16

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**	95.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○ No ●

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

PC Time Stamp	16 AUG 2020 11:03
PC Open Date & Time	16 AUG 2020 10:40
PC Close Date & Time	16 AUG 2020 13:10

FDA-CBER-2022-1614-0407431

TIMEPOINT	DAY 1, AFTER VACCINATION
	(AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	16 AUG 2020 22:31
PC Open Date & Time	16 AUG 2020 14:05
PC Close Date & Time	17 AUG 2020 11:59

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	17 AUG 2020 17:30
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE** in °F	96.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	18 AUG 2020 23:09
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:16

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**	95.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	19 AUG 2020 19:28
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 5

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

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

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

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

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

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

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

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

PC Time Stamp	20 AUG 2020 20:31
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

TIMEPOINT	DAY 6

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

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

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

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

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

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

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

| Please record your **TEMPERATURE in °F** | 95.0 °F |

| Was any **MEDICATION TAKEN today for pain or fever**? | Yes ○ |
| | No ● |

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

PC Time Stamp	21 AUG 2020 14:24
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.0 °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	22 AUG 2020 14:10
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

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	16 AUG 2020 10:40
PC Close Date & Time	16 AUG 2020 13:10

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	16 AUG 2020 14:06
PC Open Date & Time	16 AUG 2020 14:05
PC Close Date & Time	17 AUG 2020 11:59

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 2

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 ⬤ |

| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ◯ |
| | No ⬤ |

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	17 AUG 2020 17:30
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

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	18 AUG 2020 13:46
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 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	19 AUG 2020 19:28
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:16

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	20 AUG 2020 20:31
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:16

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	21 AUG 2020 14:24
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:16

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	22 AUG 2020 14:10
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

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 ◯

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

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

PC Time stamp	
PC Open Date & Time	16 AUG 2020 10:40
PC Close Date & Time	16 AUG 2020 13:10

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16

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	16 AUG 2020 14:07
PC Open Date & Time	16 AUG 2020 14:05
PC Close Date & Time	17 AUG 2020 11:59

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:16

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	17 AUG 2020 17:31
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:16

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	18 AUG 2020 13:46
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16

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	19 AUG 2020 19:29
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:16

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	20 AUG 2020 20:43
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16

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 ●

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16

	Yes ◯
PC Time stamp	21 AUG 2020 14:25
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:16

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	22 AUG 2020 14:11
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3192291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

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

Comments

If Contact Not Made, please provide Comments

US3192291

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3192291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **14 Feb 2021 03:48:00**

Generated On: 09 Jun 2021 15:40:16

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 02 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3192291

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 03:48:00**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ●

                                                                     No ◯

Continuing Flag   1

US3192291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 08 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3192291

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ⬤

                                                                     No ◯

Continuing Flag   1

US3192291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **09 Mar 2021 17:14:04**

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	12 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT2

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)   **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	12 SEP 2020
Time of assessment *(00:00-23:59)*	11:07 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 11:07
Temperature *(xxx.x)*	97.0 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 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

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	12 SEP 2020
Time of assessment *(00:00-23:59)*	12:39 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 12:39
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	97 mmHg
Diastolic Blood Pressure units	MMHG

US3192291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?   Yes ⬤

No ◯

Date of examination *(dd MMM yyyy)*   12 SEP 2020

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

Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **14 Feb 2021 02:36:56**
Generated On: 09 Jun 2021 15:40:16

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)*	12 SEP 2020
What was the treatment time? *(00:00-23:59)*	12:09 (24 HR)
Treatment Date and Time (derived)	12 SEP 2020 12:09
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 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **14 Feb 2021 02:36:56**
Generated On: 09 Jun 2021 15:40:16

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	12 SEP 2020
Collection time *(00:00-23:59)*	11:47 (24 HR)
Collection date and time (derived)	12 SEP 2020 11:47

US3192291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Collection date *(dd MMM yyyy)*			12 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:52	12 SEP 2020 11:52
Nasopharyngeal Swab 2	No		

US3192291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

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

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

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

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

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

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

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

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

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

PC Time Stamp	12 SEP 2020 12:30
PC Open Date & Time	12 SEP 2020 12:29
PC Close Date & Time	12 SEP 2020 14:59

FDA-CBER-2022-1614-0407477

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	95.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	12 SEP 2020 20:01
PC Open Date & Time	12 SEP 2020 15:54
PC Close Date & Time	13 SEP 2020 11:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:16

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**	95.0 °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	13 SEP 2020 19:33
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 3

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

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

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

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

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

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

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

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

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

PC Time Stamp	14 SEP 2020 19:08
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:16

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**	97.4 °F

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

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

PC Time Stamp	16 SEP 2020 08:19
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.0 °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	16 SEP 2020 21:03
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:16

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**	97.4 °F

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

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

PC Time Stamp	17 SEP 2020 17:41
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 SEP 2020 22:54
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	12 SEP 2020 12:30
PC Open Date & Time	12 SEP 2020 12:29
PC Close Date & Time	12 SEP 2020 14:59

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	12 SEP 2020 20:01
PC Open Date & Time	12 SEP 2020 15:54
PC Close Date & Time	13 SEP 2020 11:59

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16

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	13 SEP 2020 19:33
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16

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	14 SEP 2020 19:08
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 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	16 SEP 2020 08:20
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 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	16 SEP 2020 21:04
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 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	17 SEP 2020 17:41
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 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	18 SEP 2020 22:54
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16

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 ◯

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	12 SEP 2020 12:31
PC Open Date & Time	12 SEP 2020 12:29
PC Close Date & Time	12 SEP 2020 14:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16

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	◯

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	12 SEP 2020 20:02
PC Open Date & Time	12 SEP 2020 15:54
PC Close Date & Time	13 SEP 2020 11:59

Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16

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 ●

PRODUCTION RELEASE (v12.003 EAB) (1725)

Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16

	Yes ◯
PC Time stamp	13 SEP 2020 19:34
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16

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 ●

PRODUCTION RELEASE (v12.003 EAB) (1725)

FDA-CBER-2022-1614-0407499

	Yes ◯
PC Time stamp	14 SEP 2020 19:08
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16

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	16 SEP 2020 08:20
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16

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	16 SEP 2020 21:04
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

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	17 SEP 2020 17:42
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

TIMEPOINT	DAY 7

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

	Yes ◯
PC Time stamp	18 SEP 2020 22:55
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3192291

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **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 ◯

PC Time Stamp	19 SEP 2020 21:08
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3192291

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **FATIGUE**	None ◯
	No interference with activity ⬤
	Some interference with activity ◯
	Significant; prevents daily activity ◯
PC Time Stamp	19 SEP 2020 21:08
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3192291

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 9
Select one response below to indicate the intensity of your **FATIGUE**	None ⬤
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
PC Time Stamp	21 SEP 2020 07:12
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3192291
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	19 SEP 2020 21:08
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3192291

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	21 SEP 2020 07:12
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3192291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4)   **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3192291

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ⬤

                                                                                                    No ◯

Continuing Flag   1

US3192291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3192291

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?　　　　　　　　　　Yes ●

No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3192291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **09 Mar 2021 17:14:04**

Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	03 OCT 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3192291

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3192291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **09 Mar 2021 17:14:04**

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	10 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT3

US3192291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	10 OCT 2020
Time of assessment *(00:00-23:59)*	11:46 (24 HR)
Vital Signs Date and Time (derived)	10 OCT 2020 11:46
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	67 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?   Yes ●

                                                                            No ◯

Date of examination *(dd MMM yyyy)*   10 OCT 2020

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

US3192291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4)   **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	10 OCT 2020
Collection time *(00:00-23:59)*	12:08 (24 HR)
Collection date and time (derived)	10 OCT 2020 12:08

US3192291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:36:56**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 OCT 2020 08:20:59
Patient Cloud Open Date & Time	16 OCT 2020 00:01
Patient Cloud Close Date & Time	20 OCT 2020 23:59

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 03:03:28
Patient Cloud Open Date & Time	23 OCT 2020 00:01
Patient Cloud Close Date & Time	27 OCT 2020 23:59

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	**DAY 78**

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately	◯
Date and time of submission		
Patient Cloud Open Date & Time	30 OCT 2020 00:01	
Patient Cloud Close Date & Time	03 NOV 2020 23:59	

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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 ⚪
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	13 NOV 2020 14:35:29
Patient Cloud Open Date & Time	13 NOV 2020 00:01
Patient Cloud Close Date & Time	17 NOV 2020 23:59

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⬤
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ⚪
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	20 NOV 2020 19:10:24
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

FDA-CBER-2022-1614-0407530

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ◯
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	24 NOV 2020 12:50:21
Patient Cloud Open Date & Time	24 NOV 2020 00:01
Patient Cloud Close Date & Time	28 NOV 2020 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ○
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	01 DEC 2020 20:39:19
Patient Cloud Open Date & Time	01 DEC 2020 00:01
Patient Cloud Close Date & Time	05 DEC 2020 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	10 DEC 2020 13:04:12
Patient Cloud Open Date & Time	08 DEC 2020 00:01
Patient Cloud Close Date & Time	12 DEC 2020 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	17 DEC 2020 15:12:36
Patient Cloud Open Date & Time	15 DEC 2020 00:01
Patient Cloud Close Date & Time	19 DEC 2020 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	22 DEC 2020 12:05:53
Patient Cloud Open Date & Time	22 DEC 2020 00:01
Patient Cloud Close Date & Time	26 DEC 2020 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	29 DEC 2020 01:52:33
Patient Cloud Open Date & Time	29 DEC 2020 00:01
Patient Cloud Close Date & Time	02 JAN 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	05 JAN 2021 10:03:38
Patient Cloud Open Date & Time	05 JAN 2021 00:01
Patient Cloud Close Date & Time	09 JAN 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	12 JAN 2021 10:30:30
Patient Cloud Open Date & Time	12 JAN 2021 00:01
Patient Cloud Close Date & Time	16 JAN 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	21 JAN 2021 11:49:37
Patient Cloud Open Date & Time	19 JAN 2021 00:01
Patient Cloud Close Date & Time	23 JAN 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	27 JAN 2021 13:19:28
Patient Cloud Open Date & Time	26 JAN 2021 00:01
Patient Cloud Close Date & Time	30 JAN 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	02 FEB 2021 09:25:02
Patient Cloud Open Date & Time	02 FEB 2021 00:01
Patient Cloud Close Date & Time	06 FEB 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 14:24:12
Patient Cloud Open Date & Time	09 FEB 2021 00:01
Patient Cloud Close Date & Time	13 FEB 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	17 FEB 2021 10:45:00
Patient Cloud Open Date & Time	16 FEB 2021 00:01
Patient Cloud Close Date & Time	20 FEB 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	23 FEB 2021 10:36:02
Patient Cloud Open Date & Time	23 FEB 2021 00:01
Patient Cloud Close Date & Time	27 FEB 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	02 MAR 2021 15:48:08
Patient Cloud Open Date & Time	02 MAR 2021 00:01
Patient Cloud Close Date & Time	06 MAR 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	11 MAR 2021 14:22:15
Patient Cloud Open Date & Time	09 MAR 2021 00:01
Patient Cloud Close Date & Time	13 MAR 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	16 MAR 2021 08:12:47
Patient Cloud Open Date & Time	16 MAR 2021 00:01
Patient Cloud Close Date & Time	20 MAR 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 09:19:22
Patient Cloud Open Date & Time	23 MAR 2021 00:01
Patient Cloud Close Date & Time	27 MAR 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 MAR 2021 10:21:36
Patient Cloud Open Date & Time	30 MAR 2021 00:01
Patient Cloud Close Date & Time	03 APR 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	06 APR 2021 13:54:10
Patient Cloud Open Date & Time	06 APR 2021 00:01
Patient Cloud Close Date & Time	10 APR 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	16 APR 2021 18:16:17
Patient Cloud Open Date & Time	13 APR 2021 00:01
Patient Cloud Close Date & Time	17 APR 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	20 APR 2021 07:59:37
Patient Cloud Open Date & Time	20 APR 2021 00:01
Patient Cloud Close Date & Time	24 APR 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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	27 APR 2021 10:54:20
Patient Cloud Open Date & Time	27 APR 2021 00:01
Patient Cloud Close Date & Time	01 MAY 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 264

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

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

Fever (Temperature $\geq$ 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 ◯

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US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0407558

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 285

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

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

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

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

FDA-CBER-2022-1614-0407560

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ◯

FDA-CBER-2022-1614-0407562

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 306

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

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

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	**DAY 313**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Symptom	
Fever (Temperature $\geq$ 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 ⭕

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	**DAY 327**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

DAY 334

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

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

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-2022-1614-0407574

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 $\geq$ 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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ⚪

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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):

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-2022-1614-0407580

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-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 ⬭

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 369

| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ⚪ |
| | Yes ⚪ |

| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No ⚪ |
| | Yes ⚪ |

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

| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No ⚪ |
| | Yes ⚪ |

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

Fever (Temperature $\geq$ 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 ⚪ |

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 376

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

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

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-2022-1614-0407586

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 $\geq$ 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 ⭕

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-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 ⚪

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ⭕

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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):

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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 $\geq$ 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 ⭕

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT DAY 418

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

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

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT DAY 432

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

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

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

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

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	**DAY 439**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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-2022-1614-0407604

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 446

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

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

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 NOV 2021 00:01
Patient Cloud Close Date & Time	06 NOV 2021 23:59

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0407608

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ◯

FDA-CBER-2022-1614-0407610

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 467

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

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

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	**DAY 474**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ⬭

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT DAY 495

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

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

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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-2022-1614-0407626

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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):

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 ⬭

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	**DAY 530**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 $\geq$ 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 ⬭

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	**DAY 551**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?　　No ◯　Yes ◯

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?　　No ◯　Yes ◯

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?　　No ◯　Yes ◯

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?　　No ◯　Yes ◯

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ◯

PRODUCTION RELEASE (v12.003 EAB) (1725)   243 of 4019

FDA-CBER-2022-1614-0407638

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ⭕

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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):

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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-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 ⚪

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 $\geq$ 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 ⬭

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 600

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

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT DAY 607

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

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

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

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

FDA-CBER-2022-1614-0407652

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	**DAY 614**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 $\geq$ 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 ⬭

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0407658

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0407660

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ○

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ◯

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

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

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

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

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 684

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

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

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 ⬭

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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):

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 ⭕

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 $\geq$ 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-2022-1614-0407678

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 705

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

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

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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 712

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

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

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0407684

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-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 ⬭

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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):

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 ◯

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

DAY 740

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

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

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT	**DAY 754**

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

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

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

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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):

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-2022-1614-0407696

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 ○

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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-2022-1614-0407700

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0407702

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT DAY 789

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

FDA-CBER-2022-1614-0407704

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT   DAY 796

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

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

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 ◯

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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

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		19 MAR 2021 18:00:54

US3192291
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **09 Mar 2021 17:14:04**
Generated On: 09 Jun 2021 15:40:16

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 NOV 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3192291

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **09 Mar 2021 17:14:04**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3192291

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **03 Apr 2021 15:18:38**

Generated On: 09 Jun 2021 15:40:16

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 11 DEC 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3192291

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **03 Apr 2021 15:18:38**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3192291
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **03 Apr 2021 23:49:40**
Generated On: 09 Jun 2021 15:40:16

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 11 JAN 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3192291

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **03 Apr 2021 23:49:40**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3192291
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **03 Apr 2021 23:49:40**
Generated On: 09 Jun 2021 15:40:16

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   _____

US3192291

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **03 Apr 2021 23:49:40**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3192291

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) **03 Apr 2021 15:18:41**

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?	Yes ⬤
	No ◯
Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤
Folder OID	VISIT4

US3192291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **03 Apr 2021 15:18:41**

Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	19 MAR 2021
Time of assessment *(00:00-23:59)*	10:50 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 10:50
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **03 Apr 2021 15:18:41**

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?

Yes ⬤

No ◯

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

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

Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **03 Apr 2021 15:18:41**
Generated On: 09 Jun 2021 15:40:16

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	19 MAR 2021
Collection time *(00:00-23:59)*	10:50 (24 HR)
Collection date and time (derived)	19 MAR 2021 10:50

US3192291

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **03 Apr 2021 15:18:41**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3192291

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) **15 Apr 2021 15:33:38**

Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 APR 2021
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments _____

US3192291

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **15 Apr 2021 15:33:38**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3192291
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

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 _____

Is the participant continuing to the next visit?   Yes ◯
                                                                                  No ◯

Continuing Flag

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID-19 Contact
Data signed: (b) (4) **03 Apr 2021 23:48:56**
Generated On: 09 Jun 2021 15:40:16

Date of Contact	28 OCT 2020
Time of Contact	15:00
Date and Time of Contact (derived)	28 OCT 2020 15:00
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 ◯

Symptom Day   Day 1 ⬤

Day 2 ◯

Day 3 ◯

Day 4 ◯

Day 5 ◯

Day 6 ◯

Day 7 ◯

Day 8 ◯

Day 9 ◯

Day 10 ◯

Day 11 ◯

Day 12 ◯

Day 13 ◯

Day 14 ◯

Day 15 ◯

Day 16 ◯

Day 17 ◯

Day 18 ◯

Day 19 ◯

Day 20 ◯

Day 21 ◯

Day 22 ◯

Day 23 ◯

Day 24 ◯

Day 25 ◯

Day 26 ◯

Day 27 ◯

Day 28 ◯

Day 29 ◯

Day 30 ◯

Day 31 ◯

Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	27 OCT 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	97.0 F
Chills	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (2)
Data signed: (b) (4) **03 Apr 2021 23:48:56**
Generated On: 09 Jun 2021 15:40:16

Symptom Day	
	Day 1 ◯
	Day 2 ⬤
	Day 3 ◯
	Day 4 ◯
	Day 5 ◯
	Day 6 ◯
	Day 7 ◯
	Day 8 ◯
	Day 9 ◯
	Day 10 ◯
	Day 11 ◯
	Day 12 ◯
	Day 13 ◯
	Day 14 ◯
	Day 15 ◯
	Day 16 ◯
	Day 17 ◯
	Day 18 ◯
	Day 19 ◯
	Day 20 ◯
	Day 21 ◯
	Day 22 ◯
	Day 23 ◯
	Day 24 ◯
	Day 25 ◯
	Day 26 ◯
	Day 27 ◯
	Day 28 ◯
	Day 29 ◯
	Day 30 ◯
	Day 31 ◯
	Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	28 OCT 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) **03 Apr 2021 23:48:56**

Generated On: 09 Jun 2021 15:40:16

	Not Done ○
Fatigue	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
Muscle Aches (Myalgia)	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
Body Aches	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
Headache	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
New Loss of Taste	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
New Loss of Smell	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ○
Mild ●
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ○
Mild ●
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3192291

Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (3)
Data signed: (b) (4) **03 Apr 2021 23:48:56**
Generated On: 09 Jun 2021 15:40:16

Symptom Day

Day 1	◯
Day 2	◯
Day 3	⬤
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	29 OCT 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	101.1 F
Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ⬤
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

US3192291

Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (3)
Data signed: (b) (4) **03 Apr 2021 23:48:56**
Generated On: 09 Jun 2021 15:40:16

Not Done ⭕

Fatigue

None ⭕
Mild ⭕
Moderate ⭕
Severe 🔘
Not Done ⭕

Muscle Aches (Myalgia)

None ⭕
Mild ⭕
Moderate ⭕
Severe 🔘
Not Done ⭕

Body Aches

None ⭕
Mild ⭕
Moderate ⭕
Severe 🔘
Not Done ⭕

Headache

None ⭕
Mild ⭕
Moderate 🔘
Severe ⭕
Not Done ⭕

New Loss of Taste

None ⭕
Mild ⭕
Moderate 🔘
Severe ⭕
Not Done ⭕

New Loss of Smell

None ⭕
Mild ⭕
Moderate 🔘
Severe ⭕
Not Done ⭕

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ○
Mild ●
Moderate ○
Severe ○
Not Done ○

Vomiting

None ○
Mild ○
Moderate ●
Severe ○
Not Done ○

Diarrhea

None ○
Mild ○
Moderate ●
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **03 Apr 2021 23:48:56**
Generated On: 09 Jun 2021 15:40:16

Date of Visit	29 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ⬤
	No ◯
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ◯
	No ⬤
Date of Test	29 OCT 2020
Type of Test Performed	Nasopharyngeal Swab ⬤
	Nasal Swab ◯
	Saliva Test ◯
	Other ◯
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ◯
	No ⬤
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ◯
	No ◯
COVID-19 Positive (CSA Programming Field Only)	0

Generate Next COVID-19 Assessment	Yes $\bigcirc$
	No $\bigcirc$

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3192291
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **03 Apr 2021 15:18:37**
Generated On: 09 Jun 2021 15:40:16

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	29 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SICKD1

US3192291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?	Yes ⬤
	No ⭕
Date of assessment *(dd MMM yyyy)*	29 OCT 2020
Time of assessment *(00:00-23:59)*	17:25 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 17:25
Height *(xxx.x)*	61 in
Weight *(xxx.x)*	158.2 lb
Temperature *(xxx.x)*	99.1 F
Route of measurement	Oral ⬤
	Axillary ⭕
	Other ⭕
If Other, specify	
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192291

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?	Yes ●
	No ◯

Date of examination *(dd MMM yyyy)*	29 OCT 2020

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

US3192291

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ●
	No ◯
	NA (COVID-19 Negative) ◯
Date of Collection	29 OCT 2020

US3192291

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

Form: Visit Date

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	22 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	UNBLND_DECIDE

US3192291

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

Form: Unblinding

Data signed: (b) (4) **12 Apr 2021 17:53:54**

Generated On: 09 Jun 2021 15:40:16

Date of updated informed consent *(dd MMM yyyy)*	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ⬤
	No ◯
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ◯
	Amendment 6 or later ⬤
Date of unblinding *(dd MMM yyyy)*	22 JAN 2021
Participant randomization assignment	mRNA-1273 ◯
	Placebo ⬤
Actual Dose 1	mRNA-1273 ◯
	Placebo ⬤
	Not Administered ◯
Actual Dose 2	mRNA-1273 ◯
	Placebo ⬤
	Not Administered ◯
Will participant receive mRNA-1273?	Yes ⬤
	No ◯
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3192291

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

Form: Vital Signs - Dosing

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Height	61 in
Weight	153 lb
BMI (xxx.x)	28.96954

US3192291

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Height	61 in
Weight	153 lb
BMI *(xxx.x)*	28.96954
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	22 JAN 2021
Time of assessment *(00:00-23:59)*	08:41 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 08:41
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	91 mmHg
Diastolic Blood Pressure units	MMHG

US3192291

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Height	61 in
Weight	153 lb
BMI *(xxx.x)*	28.96954
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	22 JAN 2021
Time of assessment *(00:00-23:59)*	09:42 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 09:42
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	58 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

US3192291

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

Form: Physical Examination

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?   Yes ⬤

No ◯

Date of examination *(dd MMM yyyy)*   22 JAN 2021

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

Was study treatment given?	Yes ⬤
	No ◯

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

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	22 JAN 2021
What was the treatment time? *(00:00-23:59)*	09:07 (24 HR)
Treatment Date and Time (derived)	22 JAN 2021 09:07
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: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	22 JAN 2021
Collection time *(00:00-23:59)*	08:57 (24 HR)
Collection date and time (derived)	22 JAN 2021 08:57

US3192291

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	22 JAN 2021
Collection time *(00:00 - 23:59)*	08:53
Collection Date and Time (derived)	22 JAN 2021 08:53

US3192291

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

Form: Continuing

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3192291

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **03 Apr 2021 15:18:41**

Generated On: 09 Jun 2021 15:40:16

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 1 FEB 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3192291

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **03 Apr 2021 15:18:41**

Generated On: 09 Jun 2021 15:40:16

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

Continuing Flag	1
OLD29 Placebo Flag	1

US3192291
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **03 Apr 2021 15:18:37**
Generated On: 09 Jun 2021 15:40:16

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	19 FEB 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)*	19 FEB 2021
Time of assessment *(00:00-23:59)*	08:41 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 08:41
Temperature *(xxx.x)*	97.4 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	79 mmHg
Diastolic Blood Pressure units	MMHG

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	19 FEB 2021
Time of assessment *(00:00-23:59)*	09:42 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 09:42
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	62 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG

US3192291

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?   Yes ●

     No ○

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

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

Was study treatment given?	Yes ●
	No ○

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

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	19 FEB 2021
What was the treatment time? *(00:00-23:59)*	09:10 (24 HR)
Treatment Date and Time (derived)	19 FEB 2021 09:10
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

US3192291

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ●

                                                                                                              No ◯

Continuing Flag   1

US3192291

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) **03 Apr 2021 15:18:41**

Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	1 MAR 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3192291

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) **03 Apr 2021 15:18:38**

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?   Yes ●

                                                                                      No ○

Continuing Flag   1

US3192291

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?	Yes ●
	No ○

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

Folder OID	OLD57

US3192291

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4)　03 Apr 2021 15:18:37

Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	19 MAR 2021
Time of assessment *(00:00-23:59)*	10:50 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 10:50
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192291

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) **03 Apr 2021 15:18:37**

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?   Yes ●

                                                        No ○

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

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

Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **03 Apr 2021 15:18:37**
Generated On: 09 Jun 2021 15:40:16

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	19 MAR 2021
Collection time *(00:00-23:59)*	10:58 (24 HR)
Collection date and time (derived)	19 MAR 2021 10:58

US3192291

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **12 Apr 2021 17:53:54**

Generated On: 09 Jun 2021 15:40:16

Did the participant experience any adverse events?   Yes ⬤

                                                          No ◯

If Yes, enter details on the Adverse Events form.

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	USA-US097-2020-MRNA-1273-P30 1000004
Adverse event	C-DIFF - COLITIIS
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)*	2 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	10 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ●
Is the adverse event serious?	Yes ●
	No ○
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	2 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	10 NOV 2020
Admitted to ICU?	Yes ●
	No ○
	Unknown ○

Number of Days in ICU	3
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

FDA-CBER-2022-1614-0407772

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

	PATIENT REPORTED TO CLINIC HAVING COVID LIKE SYMPTOMS - COVID TEST NEGATIVE. ADMITTED TO HOSPITAL AND SENT HOME WITH ANTIBIOTICS. SYMPTOMS REPORTED WERE NAUSEA, VOMITING, DIARRHEA, AND FEVERS. REASON SITE DID AN ILLNESS VISIT.
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)	1

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	RASH AND ITCHING FROM NORVASC
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)*	14 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	09 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ●
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○

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

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

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

Other action taken (check all that apply)

None	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	
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)	

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4)　30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:40:16

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

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

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

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

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

Other action taken (check all that apply)

None	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	
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)	

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	WORSENING HYPERTENSION
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	09 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	10 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

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

AEID	
Adverse event	HYPONATREMIA
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)*	03 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	08 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

AEID	
Adverse event	VOMITING
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	03 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	05 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

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

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

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

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	SORE ARM POST INJECTION
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)*	22 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ⚪
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	22 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ⚪
	Grade 3/Severe ⚪
	Grade 4 ⚪
Is the adverse event serious?	Yes ⚪
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ⚪
	No ⚪
	Unknown ⚪
Number of Days in ICU	

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

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

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

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

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

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

Other action taken (check all that apply)

None	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	
Serious Adverse Event Derived (CSA Programming Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	GASTROENTERITIS
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)	03 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date (dd MMM yyyy)	10 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ◯
	Grade 3/Severe ⬤
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤

AE is serious due To (check all that apply)

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

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

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

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

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

Other action taken (check all that apply)

None	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	
Serious Adverse Event Derived (CSA Programming Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

Folder: Adverse Events
Form: Adverse Events (10)
Data signed: (b) (4)   **30 Apr 2021 20:43:25**
Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	FATIGUE
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)*	12 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	19 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ◯
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4)   **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	HYPOTENSION
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)*	03 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	08 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	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	
Serious Adverse Event Derived (CSA Programming Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

AEID	
Adverse event	SHORTNESS OF BREATH
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)*	03 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	08 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	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	
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)	

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	FEVER
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)*	29 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	04 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

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

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

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

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

Narrative _____

Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	FATIGUE
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)*	29 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	04 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	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	
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)	

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	03 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	10 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

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

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

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

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

AEID	
Adverse event	NAUSEA/VOMITING
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	28 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	10 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

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

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4)   **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	ALTERED MENTAL STATUS
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)*	03 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	05 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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

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

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

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

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

AEID	
Adverse event	WORSENING HYPERTENSION
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	09 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	10 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

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

Relationship to investigational product	Not Related ⬤
	Related ◯
	Not Applicable ◯
Relationship to Study Procedure	Not Related ⬤
	Related ◯
	Not Applicable ◯
Action taken with investigational product	None ◯
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

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

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:40:16

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

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

Relationship to investigational product

- ⬤ Not Related
- ◯ Related
- ◯ Not Applicable

Relationship to Study Procedure

- ⬤ Not Related
- ◯ Related
- ◯ Not Applicable

Action taken with investigational product

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

Other action taken (check all that apply)

None	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	
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)	

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	HYPOTENSION
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)*	07 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	08 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤

AE is serious due To (check all that apply)

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

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EAB) (1725)

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	
Serious Adverse Event Derived (CSA Programming Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

Folder: Adverse Events

Form: Adverse Events (22)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	SEVERE TRICUSPID VALVE REGURGITATION
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	09 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	10 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○

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

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

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

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	EDEMA
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	09 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	10 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ●
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

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

AEID	
Adverse event	BLADDER SPASMS
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date (dd MMM yyyy)	08 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date (dd MMM yyyy)	09 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ◯
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

Folder: Adverse Events

Form: Adverse Events (24)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

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

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

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

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	MILD HYPONATREMIA
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)*	24 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	29 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ◯
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

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

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	VOMITING
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	24 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	29 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤

AE is serious due To (check all that apply)

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

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

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

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

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	IRRITABLE BOWEL SYNDROME
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	05 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ●
	No ○
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ●
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	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	
Serious Adverse Event Derived (CSA Programming Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	LOOSE STOOLS
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	26 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	29 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

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

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

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

Other action taken (check all that apply)

None	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	
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)	

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:40:16

AEID	
Adverse event	GENERALIZED WEAKNESS
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)*	24 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	29 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	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	
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)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **03 Apr 2021 23:48:56**

Generated On: 09 Jun 2021 15:40:16

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

No ○

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

Name of Medication	MACROBID

Prophylaxis	Yes ⚪
	No ⚫

Indication	URINARY TRACT INFECTION

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 ⚪

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	13 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ⚪
	No ⚫
If not Ongoing, End date *(dd MMM yyyy)*	19 AUG 2020
Was this medication taken for solicited event?	Yes ⚪
	No ⚫
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⚪
	803 ⚪
	804 ⚫

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	SPIROLACTONE

Prophylaxis	
Yes	◯
No	⬤

Indication	HYPERTENSION
Dose per administration	25

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

PRODUCTION RELEASE (v12.003 EAB) (1725)

438 of 4019

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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 1995
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   HYPERTENSION

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 ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

	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 1995
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 (4)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	CRESTOR

Prophylaxis	
	Yes ◯
	No ⬤

Indication	HYPERCHOLESTEROLEMIA
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)

US3192291

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

	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 1990
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 ●

FDA-CBER-2022-1614-0407838

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	MELOXICAM

Prophylaxis	
Yes	◯
No	⬤

Indication	OSTEOARTHRITIS
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	◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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 1995
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	LAMICTAL
Prophylaxis	Yes ○
	No ●

Indication	BIPLOAR DISORDER
Dose per administration	100

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1990
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 (7)

Data signed:　(b) (4)　**25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	ANAFRANIL

Prophylaxis

Yes ◯
No ⬤

Indication	BIPOLAR DISORDER
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　TWICE A WEEK

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 UNK 1995

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 (8)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

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

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 UNK 1992
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)	2
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	GABAPENTIN

Prophylaxis

Yes ◯
No ⬤

Indication	OBSESSIVE COMPULSIVE DISORDER/BIPOLAR DISORDER
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	TWICE A WEEK

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4)   **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	BUSPAR
Prophylaxis	Yes ◯
	No ⬤

Indication	BIPOLAR DISORDER
Dose per administration	10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	4
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 (11)

Data signed: (b) (4)   **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	HYDROCODONE/APAP

Prophylaxis

Yes ◯

No ⬤

Indication	OSTEOARTHRITIS
Dose per administration	7.5/500

Dose unit

mg ⬤

ug ◯

mL ◯

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify

Frequency

once daily ◯

twice daily ◯

three times daily ◯

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ⬤

once ◯

unknown ◯

other ◯

If frequency is Other, specify

Route of administration

Oral ⬤

Topical ◯

Subcutaneous ◯

Transdermal ◯

Intraocular ◯

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 UNK 2019

Start date completely unknown — False

Ongoing? — Yes ⬤ / No ◯

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

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

Separate Dosage Number (derived) _____

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) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	ESTRADIOL
Prophylaxis	Yes ●
	No ○
Indication	POST MENOPAUSAL
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 ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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 1995
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 ●

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1995
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) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	NORVASC
Prophylaxis	Yes ○
	No ●
Indication	HYPERTENSION
Dose per administration	2.5
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 ○

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	2 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	4 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	VANCOMYCIN

Prophylaxis	Yes ⚪
	No ⬤

Indication	C-DIFF
Dose per administration	125

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	2 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	10 NOV 2020
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 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	NORVASC
Prophylaxis	Yes ⭕
	No ⬤
Indication	WORSENING HYPERTENSION
Dose per administration	2.5
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 ⭕

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Data signed: (b) (4)   **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

	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)*	02 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬛
If not Ongoing, End date *(dd MMM yyyy)*	04 JAN 2021
Was this medication taken for solicited event?	Yes ⬭
	No ⬛
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬛

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

Name of Medication	VANCOMYCIN

Prophylaxis	
	Yes ◯
	No ⬤

Indication	C.DIFF COLITIS
Dose per administration	125

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	10 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	20 NOV 2020
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 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	IBUPROFEN

Prophylaxis	
Yes	○
No	●

Indication	CHILLS, FEVER
Dose per administration	400

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

FDA-CBER-2022-1614-0407865

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	29 OCT 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	TYLENOL

Prophylaxis	Yes	◯
	No	⬤

Indication	CHILLS, FEVER
Dose per administration	500

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

If dose unit is Other, specify	_____

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

If frequency is Other, specify	_____

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	29 OCT 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	ZOFRAN
Prophylaxis	Yes ○
	No ●
Indication	NAUSEA/VOMITING
Dose per administration	3
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ●
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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)*	01 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	02 NOV 2020
Was this medication taken for solicited event?	Yes ○
	No ⬤

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

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	ZOFRAN

Prophylaxis

Yes ⚪

No ⚫

Indication	NAUSEA/VOMITING
Dose per administration	4

Dose unit

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

If dose unit is Other, specify _____

Frequency

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

If frequency is Other, specify _____

Route of administration

Oral ⚪
Topical ⚪
Subcutaneous ⚪
Transdermal ⚪
Intraocular ⚪

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)*	03 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	03 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4)   **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	NP BOLUS

Prophylaxis	Yes ⭘
	No ⬤

Indication	HYDRATION/NAUSEA/VOMITING

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 ⭘

FDA-CBER-2022-1614-0407873

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Data signed: (b) (4)   **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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)*	03 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	03 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	DEXTROSE
Prophylaxis	Yes ⬭
	No ⬤
Indication	DEHYDRATION
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)*	03 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	07 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

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

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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)*	03 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	07 NOV 2020
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 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	CLOMIPRAMINE
Prophylaxis	Yes ◯
	No ⬤

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

Name of Medication	HEPARIN

Prophylaxis	Yes ○
	No ●

Indication	PREVENTION OF BLOOD CLOTS

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 ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

	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)*	03 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	09 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	ATIVAN

Prophylaxis Yes ◯
No ⬤

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	AMOLODIPINE

Prophylaxis
Yes ◯
No ⬤

Indication	WORSENING HYPERTENSION
Dose per administration	5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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)*	08 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	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 (30)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	LASIX

Prophylaxis

Yes ◯
No ⬤

Indication	SEVERE TRICUSPID REGURGITATION/EDEMA
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 ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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

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

FDA-CBER-2022-1614-0407888

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	MAGNESIUM SULFATE

Prophylaxis

Yes ⭘
No ⬤

Indication	ELECTROLYTE REPLACEMENT
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 ⭘

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	09 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	10 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	SOLIFENACIN

Prophylaxis

Yes ◯
No ⬤

Indication	BLADDER SPASMS
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)

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	09 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	10 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	PROGESTERONE

Prophylaxis	
	Yes ◯
	No ⬤

Indication	POST MENOPAUSE
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 ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯

If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	ZOFRAN

Prophylaxis	Yes ⚪
	No ⚫

Indication	VOMITING

Dose per administration	8

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 ⚪

FDA-CBER-2022-1614-0407895

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 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	29 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-0407896

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

Name of Medication	POTASSIUM CHLORIDE

Prophylaxis
- Yes ⚪
- No ⬤

Indication	MILD HYPONATREMIA
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	3X A WEEK

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 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	29 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) **25 Apr 2021 17:52:28**

Generated On: 09 Jun 2021 15:40:16

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

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Data signed: (b) (4) **25 Apr 2021 17:52:28**
Generated On: 09 Jun 2021 15:40:16

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	26 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	26 NOV 2020
Was this medication taken for solicited event?	Yes ⬭
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬭

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Were any concomitant procedures performed?   Yes ●

No ◯

If yes, please complete Concomitant Procedures form.

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **23 Apr 2021 14:19:18**

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
27 OCT 2020	TOOTH EXTRACTION	Other	DENTAL
27 OCT 2020	DENTAL BRIDGE PROCEDURE	Other	DENTAL WORK
03 NOV 2020	CHEST X-RAY	Diagnostic	
03 NOV 2020	EKG	Diagnostic	
03 NOV 2020	ULTRASOUND RETROPERITONEAL KIDNEY	Diagnostic	
10 NOV 2020	ECHO	Diagnostic	
04 NOV 2020	CT ABDOMEN W/O CONTRAST	Diagnostic	
09 NOV 2020	CHEST X-RAY	Diagnostic	
03 NOV 2020	NUCLEAR MEDICINE PULMONARY VENTILATION AND PERFUSION STUDY	Diagnostic	

Date of dosing discontinuation (dd MMM yyyy) _____

Primary reason for dosing discontinuation

AE (specify)	◯
SAE (specify)	◯
Death	◯
Lost To Follow-up	◯
Physician decision (specify)	◯
Pregnancy	◯
Protocol deviation (specify)	◯
Study Terminated By Sponsor	◯
Withdrawal of consent by participant (specify)	◯
Due to SARS-COV-2	◯
Other	◯

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify _____

FDA-CBER-2022-1614-0407903

Date of study discontinuation/completion *(dd MMM yyyy)* _____

Reason for discontinuation

AE (specify) ◯
SAE (specify) ◯
Complete ◯
Death ◯
Lost To Follow-up ◯
Physician decision (specify) ◯
Pregnancy ◯
Protocol deviation (specify) ◯
Study Terminated By Sponsor ◯
Withdrawal of consent by participant (specify) ◯
Other ◯

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify _____

If reason for discontinuation is Death, main cause of death

Adverse event ◯
Unknown ◯
Other ◯

If main cause of death is Other, specify _____

Date of death *(dd MMM yyyy)* _____

Was autopsy performed?

Yes ◯
No ◯
Unknown ◯

SAEID	USA-US097-2020-MRNA-1273-P30 1000004
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) **08 Apr 2021 19:44:34**

Generated On: 09 Jun 2021 15:40:16

SAEID	USA-US097-2020-MRNA-1273-P30 1000004
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/NOV/2020 22:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) **08 Apr 2021 19:44:34**

Generated On: 09 Jun 2021 15:40:16

SAEID	USA-US097-2020-MRNA-1273-P30 1000004
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	03/FEB/2021 09:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

SAEID	USA-US097-2020-MRNA-1273-P30 1000004
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	03/MAR/2021 10:54
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-US097-2020-MRNA-1273-P30 1000004
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/MAR/2021 15:49
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

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) **08 Apr 2021 19:44:34**

Generated On: 09 Jun 2021 15:40:16

SAEID	USA-US097-2020-MRNA-1273-P30 1000004
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	07/APR/2021 10:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) **08 Apr 2021 19:44:34**

Generated On: 09 Jun 2021 15:40:16

SAEID	USA-US097-2020-MRNA-1273-P30 1000004
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/APR/2021 12:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3192291 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

US3192291
Form: Participant Creation
Generated On: 09 Jun 2021 15:40:16
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'US3192291'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:44:10

US3192291

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:18:41

US3192291
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:44:11

US3192291

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Clinic (Clinic)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:18:41

US3192291
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'SCRN'	System	09 Sep 2020 04:18:41

US3192291

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:36:56
User closed query 'Per CDM: Data is required. Please complete this form ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:21:11
Query 'Per CDM: Data is required. Please complete this form ' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:54
User opened query 'Per CDM: Data is required. Please complete this form ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 08:12:24
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:44:12

US3192291
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:16

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '70'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

US3192291

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:16

Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'YEARS'	System	07 Sep 2020 22:44:51

US3192291
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:16

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '70'	System	16 Aug 2020 17:21:46

US3192291
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:16
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Female (F)'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

US3192291

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:16

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '1'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

FDA-CBER-2022-1614-0407924

US3192291

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:16

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

US3192291
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:16
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

US3192291

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:16

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:16

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

US3192291

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

US3192291

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:16

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

US3192291
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:16
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

US3192291
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:40:16
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	maggie Tono (b) (4) (b) (4)	07 Sep 2020 22:44:51

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 Aug 2020'	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:21:46

US3192291

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:16

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'Aug 2020'	System	16 Aug 2020 17:21:46

US3192291
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:16
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '2020'	System	16 Aug 2020 17:21:46

US3192291

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:16

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Amendment 1 (1)'	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:21:46

US3192291

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:16

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:21:46

US3192291

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:16

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:21:46

US3192291
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:16
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:21:46

US3192291
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:16

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:21:46

US3192291
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:16
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:44:11

US3192291
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:40:16
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '1'	System	16 Aug 2020 17:21:50

US3192291

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:40:16

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:21:50

US3192291

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:40:16

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:23:12

US3192291

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
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)	09 Sep 2020 04:30:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:30:40
Data point term sent to Coder	System	09 Sep 2020 04:29:36
Coding entries removed.	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:29:12
User entered 'hypertension' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:29:12
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:25:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:25:37
Data point term sent to Coder	System	09 Sep 2020 04:24:34
User entered 'Migraines'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:01

US3192291

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'UN UNK 1995' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:29:12
User entered 'un UNK 2005'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:01

US3192291

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:01

US3192291

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:01

US3192291

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
Signature has been broken.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:08:27
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:01

US3192291

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:01

US3192291

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'Jan 1995'	System	09 Sep 2020 04:29:12
User entered 'Jan 2005'	System	09 Sep 2020 04:24:01

US3192291

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '1995'	System	09 Sep 2020 04:29:12
User entered '2005'	System	09 Sep 2020 04:24:01

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:24:01

US3192291
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:40:16

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:24:01

US3192291
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:40:16
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:31:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:31:41
Data point term sent to Coder	System	09 Sep 2020 04:30:37
Coding entries removed.	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:29:58
User entered 'osteoarthritis' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:29:58
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:26:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:26:35
Data point term sent to Coder	System	09 Sep 2020 04:25:35
User entered 'Menopause'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:54

US3192291

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'UN UNK 1995' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:29:58
User entered 'un UNK 2001'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:54

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:54

US3192291

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:54

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:54

US3192291

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:24:54

US3192291

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'Jan 1995'	System	09 Sep 2020 04:29:58
User entered 'Jan 2001'	System	09 Sep 2020 04:24:54

US3192291

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '1995'	System	09 Sep 2020 04:29:58
User entered '2001'	System	09 Sep 2020 04:24:54

US3192291

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:16

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:24:54

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:24:54

US3192291

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Obsessive-compulsive disorders and symptoms, PT: Obsessive-compulsive disorder, LLT: Obsessive-compulsive disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:32:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:32:44
Data point term sent to Coder	System	09 Sep 2020 04:31:37
User entered 'obsessive compulsive disorder'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:38

US3192291

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'UN UNK 1990' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:01:16
User entered 'un UNK 1991'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:38

US3192291

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:38

US3192291

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:38

FDA-CBER-2022-1614-0407969

US3192291

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:38

US3192291

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'Jan 1990'	System	29 Sep 2020 20:01:16
User entered 'Jan 1991'	System	09 Sep 2020 04:30:38

US3192291

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '1990'	System	29 Sep 2020 20:01:16
User entered '1991'	System	09 Sep 2020 04:30:38

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:30:38

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:30:38

US3192291

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar II disorder, LLT: Bipolar II disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:32:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:32:44
Data point term sent to Coder	System	09 Sep 2020 04:31:37
User entered 'bipolar II'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:58

US3192291

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'UN UNK 1990' reason for change: Data Entry Error	Crystal Mata (b) (4) (b) (4)	03 Oct 2020 17:52:38
User entered 'un UNK 1991'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:58

Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:16
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:58

FDA-CBER-2022-1614-0407977

US3192291

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:58

US3192291

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:58

US3192291

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:30:58

US3192291

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'Jan 1990'	System	03 Oct 2020 17:52:38
User entered 'Jan 1991'	System	09 Sep 2020 04:30:58

US3192291

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '1990'	System	03 Oct 2020 17:52:38
User entered '1991'	System	09 Sep 2020 04:30:58

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:30:58

US3192291
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:40:16
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:30:58

US3192291

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:32:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:32:44
Data point term sent to Coder	System	09 Sep 2020 04:31:37
User entered 'hypercholesterolemia'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:31:20

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'un UNK 1990'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:31:20

FDA-CBER-2022-1614-0407986

US3192291

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:31:20

US3192291

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:31:20

US3192291

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:31:20

US3192291

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:31:20

US3192291

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'Jan 1990'	System	09 Sep 2020 04:31:20

US3192291
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:40:16
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '1990'	System	09 Sep 2020 04:31:20

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:31:20

FDA-CBER-2022-1614-0407993

US3192291
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:40:16

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:31:20

US3192291

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:33:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 04:33:45
Data point term sent to Coder	System	09 Sep 2020 04:32:38
User entered 'urinary tract infection'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:32:01

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'un Aug 2020'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:32:01

US3192291

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:32:01

US3192291

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:32:01

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:32:01

US3192291

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Saysamone Banks (b) (4) (b) (4)	09 Sep 2020 04:32:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'Aug 2020'	System	09 Sep 2020 04:32:01

US3192291
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:40:16
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '2020'	System	09 Sep 2020 04:32:01

US3192291

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:16

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:32:01

US3192291
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:40:16
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:32:01

US3192291

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:27:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:27:37
Data point term sent to Coder	System	29 Sep 2020 20:26:46
User entered 'Post Menopausal'	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:25:49

US3192291

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'un UNK 1995'	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:25:49

US3192291

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:25:49

US3192291

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:25:49

US3192291

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:25:49

US3192291

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:25:49

US3192291

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'Jan 1995'	System	29 Sep 2020 20:25:49

US3192291

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '1995'	System	29 Sep 2020 20:25:49

US3192291

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:16

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	29 Sep 2020 20:25:49

US3192291
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:40:16
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	29 Sep 2020 20:25:49

US3192291

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:24:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:24:12
Data point term sent to Coder	System	22 Apr 2021 17:22:37
User entered 'Appendectomy'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:21:38

US3192291

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:21:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:21:38

FDA-CBER-2022-1614-0408017

US3192291

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	22 Apr 2021 17:21:45
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:21:45
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	22 Apr 2021 17:21:38
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:21:38

Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:16
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:21:38

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:21:38

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:21:38

US3192291

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:21:38

US3192291

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:16

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:21:38

US3192291
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:40:16

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:21:38

US3192291

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms benign (incl nipple), HLT: Breast and nipple neoplasms benign, PT: Benign breast neoplasm, LLT: Benign breast neoplasm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 05:13:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 05:13:48
Data point term sent to Coder	System	22 Apr 2021 17:23:38
User entered 'Benign breast lesion'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:23:29

US3192291

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:23:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:23:29

US3192291

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:23:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:23:29

FDA-CBER-2022-1614-0408029

US3192291

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:23:29

US3192291
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:40:16
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:23:29

US3192291
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:40:16
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:23:29

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:23:29

FDA-CBER-2022-1614-0408033

US3192291
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:40:16
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:23:29

US3192291

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:39:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:39:08
Data point term sent to Coder	System	22 Apr 2021 17:38:50
User entered 'Osteopenia'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:37:59

US3192291

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'un UNK 1995'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:37:59

US3192291

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
	(b) (4)	
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 17:37:59
	(b) (4)	

US3192291

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:37:59

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:37:59

US3192291

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:37:59

US3192291

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'Jan 1995'	System	22 Apr 2021 17:37:59

US3192291

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '1995'	System	22 Apr 2021 17:37:59

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:37:59

US3192291

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:16

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:37:59

US3192291

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:42:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:42:01
Data point term sent to Coder	System	22 Apr 2021 17:41:05
User entered 'Anxiety'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:07

US3192291

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'un UNK 1990'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:07

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:07

US3192291

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:07

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:07

US3192291

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:07

US3192291

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'Jan 1990'	System	22 Apr 2021 17:40:07

US3192291

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '1990'	System	22 Apr 2021 17:40:07

US3192291

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:16

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:40:07

US3192291
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:40:16

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:40:07

US3192291

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:42:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:42:02
Data point term sent to Coder	System	22 Apr 2021 17:41:05
User entered 'Depression'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:19

US3192291

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'un UNK 1990'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:19

US3192291

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:19

US3192291

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:16

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	22 Apr 2021 17:40:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:22
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	22 Apr 2021 17:40:19
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:19

US3192291

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:19

US3192291

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:16

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:40:19

US3192291

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'Jan 1990'	System	22 Apr 2021 17:40:19

US3192291
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:40:16
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '1990'	System	22 Apr 2021 17:40:19

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:16

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:40:19

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	22 Apr 2021 17:40:19

US3192291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25

US3192291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25

US3192291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '11:20'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '16 Aug 2020 11:20'	System	09 Sep 2020 04:20:25

US3192291
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '64.5' in	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25
DataPoint set to visible.	System	16 Aug 2020 17:21:50

US3192291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '183.2' lb	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25
DataPoint set to visible.	System	16 Aug 2020 17:21:50

US3192291
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered '31.02530'	System	09 Sep 2020 04:20:25
DataPoint set to visible.	System	16 Aug 2020 17:21:50

US3192291
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'kg/m2'	System	09 Sep 2020 04:20:25
DataPoint set to visible.	System	16 Aug 2020 17:21:50

US3192291
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered missing code ND - Not Done.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25

US3192291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25

US3192291
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered missing code ND - Not Done.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25

US3192291
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'bpm'	System	09 Sep 2020 04:20:25

US3192291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered missing code ND - Not Done.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'breaths/min'	System	09 Sep 2020 04:20:25

US3192291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered missing code ND - Not Done.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25

US3192291
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'mmHg'	System	09 Sep 2020 04:20:25

US3192291
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered missing code ND - Not Done.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:25

US3192291
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered 'mmHg'	System	09 Sep 2020 04:20:25

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07

US3192291
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07

US3192291

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:54

US3192291

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	23 Sep 2020 01:13:14
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	23 Sep 2020 01:13:14
User entered '16 Aug 2020' reason for change: Data Entry Error	Zoe Sesma (b) (4) (b) (4)	23 Sep 2020 01:13:14
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	23 Sep 2020 01:13:09
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 01:13:09
User entered '17 Aug 2020' reason for change: Data Entry Error	Zoe Sesma (b) (4) (b) (4)	23 Sep 2020 01:13:09
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 16:36:41
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:20:54

US3192291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:16

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:21:51

US3192291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:16

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:40:38
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:21:51

US3192291
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:40:16
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:40:53
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:40:53
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:40:38
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:21:51

US3192291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:16

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:21:51

US3192291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:16

If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:21:51

US3192291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:16

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:21:51

US3192291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:16

If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'un UNK 1995' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:40:53
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:21:51

US3192291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:16

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:21:51

US3192291

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:40:16

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:07

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 Aug 2020'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:07

US3192291

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:40:16

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Urine (URINE)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:07

US3192291

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:40:16

Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Negative (NEGATIVE)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:07

US3192291

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:40:16

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:07

US3192291

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:40:16

Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:07

US3192291
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 15:40:16
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:07

US3192291

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:40:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User entered empty.	System	09 Sep 2020 04:22:07

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

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)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

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)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

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)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

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)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

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)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

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)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

FDA-CBER-2022-1614-0408112

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

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)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

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)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:16
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:16
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

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)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:16
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)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

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)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '1'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:16
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '0'	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:40:16
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:05:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Yvonne De Los Reyes (b) (4)	09 Sep 2020 04:22:50

US3192291
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:08:58

US3192291

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:08:58

US3192291
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Clinic (Clinic)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:08:58

US3192291
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'VISIT1'	System	10 Sep 2020 20:08:58

US3192291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 17:14:09

US3192291
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:40:16

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:54:19
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:54:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Aug 2020 17:14:09
User entered '186548' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 17:14:09

US3192291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:16

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 17:14:09

US3192291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:16

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)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User closed query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 13:26:52
Query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' answered with 'no' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:10:11
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:10:01
User opened query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 14:36:56

US3192291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:16

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)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:10:01

Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:10:01

US3192291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:16

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:10:01

US3192291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:16

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:10:01

US3192291
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 20:18:34
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	10 Sep 2020 20:18:34
User entered '09:45' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:34
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 20:18:23
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '16 Aug 2020 09:45'	System	10 Sep 2020 20:18:34
User entered empty.	System	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '97.4' F	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Other (Other)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'temporal'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '62'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'bpm'	System	10 Sep 2020 20:18:23

FDA-CBER-2022-1614-0408150

US3192291
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'breaths/min'	System	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '128'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'mmHg'	System	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '78'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'mmHg'	System	10 Sep 2020 20:18:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:16
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

FDA-CBER-2022-1614-0408161

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '11:00'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '16 Aug 2020 11:00'	System	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '96.9' F	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Other (Other)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:16
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'temporal'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '64'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'bpm'	System	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '14'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'breaths/min'	System	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '143'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'mmHg'	System	10 Sep 2020 20:18:23

US3192291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '95'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:18:23

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'mmHg'	System	10 Sep 2020 20:18:23

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:39

FDA-CBER-2022-1614-0408175

US3192291

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:39

US3192291
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 15:40:16

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:46

US3192291
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 15:40:16

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:46

US3192291
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 15:40:16
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:46

US3192291
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 15:40:16
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:46

US3192291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:40:16

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:46

US3192291
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 15:40:16
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:46

US3192291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:40:16

Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:46

US3192291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:40:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered empty.	System	10 Sep 2020 20:11:46

US3192291
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:16
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:22:07

US3192291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:22:07

US3192291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

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)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:22:07

US3192291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'MRNA-1273 OR PLACEBO'	System	16 Aug 2020 17:22:07

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:16

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 Aug 2020'	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:22:07

US3192291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '10:20'	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:22:07

US3192291
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:40:16

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '16 Aug 2020 10:20'	System	16 Aug 2020 17:22:07

US3192291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Right Arm (RIGHT ARM)'	Zoe Sesma (b) (4) (b) (4)	16 Aug 2020 17:22:07

FDA-CBER-2022-1614-0408192

US3192291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'ONCE'	System	16 Aug 2020 17:22:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'INTRAMUSCULAR'	System	16 Aug 2020 17:22:07

FDA-CBER-2022-1614-0408194

US3192291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:10:52

US3192291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:10:52

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '10:04'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:10:52

US3192291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '16 Aug 2020 10:04'	System	10 Sep 2020 20:10:52

US3192291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:40:16

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '16 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:12

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:16

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:12

US3192291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:16

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:12

US3192291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '10:09'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:12

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '16 Aug 2020 10:09'	System	10 Sep 2020 20:11:12

US3192291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:16

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:12

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:40:16
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:12

FDA-CBER-2022-1614-0408205

US3192291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:12

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered empty.	System	10 Sep 2020 20:11:12

US3192291
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:11:22

US3192291
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '1'	System	10 Sep 2020 20:11:22

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T11:03:23', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '506b9614-5929-4b11-a7c7-cec62e0da397'	System	16 Aug 2020 18:04:01
User entered 'Yes (Y)'	System	16 Aug 2020 18:04:01

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T11:03:37', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '506b9614-5929-4b11-a7c7-cec62e0da397'	System	16 Aug 2020 18:04:01
User entered '95.4'	System	16 Aug 2020 18:04:01

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T11:03:44', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '506b9614-5929-4b11-a7c7-cec62e0da397'	System	16 Aug 2020 18:04:01
User entered 'No (N)'	System	16 Aug 2020 18:04:01

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T11:03:59', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '506b9614-5929-4b11-a7c7-cec62e0da397'	System	16 Aug 2020 18:04:01
User entered '16 Aug 2020 11:03'	System	16 Aug 2020 18:04:01

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Aug 2020 10:40'	System	16 Aug 2020 17:22:07

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Aug 2020 13:10'	System	16 Aug 2020 17:22:07

FDA-CBER-2022-1614-0408216

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T22:31:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e1f6986e-8f61-4772-995c-db35e92c8dbc'	System	17 Aug 2020 05:31:18
User entered 'Yes (Y)'	System	17 Aug 2020 05:31:18

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T22:31:06', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e1f6986e-8f61-4772-995c-db35e92c8dbc'	System	17 Aug 2020 05:31:18
User entered '96.5'	System	17 Aug 2020 05:31:18

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T22:31:10', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e1f6986e-8f61-4772-995c-db35e92c8dbc'	System	17 Aug 2020 05:31:18
User entered 'No (N)'	System	17 Aug 2020 05:31:18

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T22:31:16', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e1f6986e-8f61-4772-995c-db35e92c8dbc'	System	17 Aug 2020 05:31:18
User entered '16 Aug 2020 22:31'	System	17 Aug 2020 05:31:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Aug 2020 14:05'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 2'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:29:52', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '194bfb70-538f-4e5a-b11f-7560010dbe82'	System	18 Aug 2020 00:30:16
User entered 'Yes (Y)'	System	18 Aug 2020 00:30:16

Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:29:59', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '194bfb70-538f-4e5a-b11f-7560010dbe82'	System	18 Aug 2020 00:30:16
User entered '96.5'	System	18 Aug 2020 00:30:16

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:30:02', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '194bfb70-538f-4e5a-b11f-7560010dbe82'	System	18 Aug 2020 00:30:16
User entered 'No (N)'	System	18 Aug 2020 00:30:16

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:30:13', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '194bfb70-538f-4e5a-b11f-7560010dbe82'	System	18 Aug 2020 00:30:16
User entered '17 Aug 2020 17:30'	System	18 Aug 2020 00:30:16

Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 3'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T23:08:45', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '9080010a-00b4-4444-b800-3c3fef86a368'	System	19 Aug 2020 06:09:03
User entered 'Yes (Y)'	System	19 Aug 2020 06:09:03

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T23:08:52', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '9080010a-00b4-4444-b800-3c3fef86a368'	System	19 Aug 2020 06:09:03
User entered '96.5'	System	19 Aug 2020 06:09:03

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T23:08:56', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '9080010a-00b4-4444-b800-3c3fef86a368'	System	19 Aug 2020 06:09:03
User entered 'No (N)'	System	19 Aug 2020 06:09:03

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:16

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T23:09:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '9080010a-00b4-4444-b800-3c3fef86a368'	System	19 Aug 2020 06:09:03
User entered '18 Aug 2020 23:09'	System	19 Aug 2020 06:09:03

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 4'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:28:17', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '24f3421c-045e-43b3-a758-d82ac1bd4b34'	System	20 Aug 2020 02:28:35
User entered 'Yes (Y)'	System	20 Aug 2020 02:28:35

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:28:24', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '24f3421c-045e-43b3-a758-d82ac1bd4b34'	System	20 Aug 2020 02:28:35
User entered '95.5'	System	20 Aug 2020 02:28:35

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:28:28', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '24f3421c-045e-43b3-a758-d82ac1bd4b34'	System	20 Aug 2020 02:28:35
User entered 'No (N)'	System	20 Aug 2020 02:28:35

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:28:34', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '24f3421c-045e-43b3-a758-d82ac1bd4b34'	System	20 Aug 2020 02:28:35
User entered '19 Aug 2020 19:28'	System	20 Aug 2020 02:28:35

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 5'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:16
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:31:03', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'c3e69ecb-b9b3-4b55-9e46-810c55fd3f1e'	System	21 Aug 2020 03:31:31
User entered 'Yes (Y)'	System	21 Aug 2020 03:31:31

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:31:14', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'c3e69ecb-b9b3-4b55-9e46-810c55fd3f1e'	System	21 Aug 2020 03:31:31
User entered '96.8'	System	21 Aug 2020 03:31:31

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:16

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:31:18', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'c3e69ecb-b9b3-4b55-9e46-810c55fd3f1e'	System	21 Aug 2020 03:31:31
User entered 'No (N)'	System	21 Aug 2020 03:31:31

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:31:27', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'c3e69ecb-b9b3-4b55-9e46-810c55fd3f1e'	System	21 Aug 2020 03:31:31
User entered '20 Aug 2020 20:31'	System	21 Aug 2020 03:31:31

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 6'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:06', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '5eec0995-9db5-493e-99b6-c81dbd4623b9'	System	21 Aug 2020 21:24:25
User entered 'Yes (Y)'	System	21 Aug 2020 21:24:25

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:15', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '5eec0995-9db5-493e-99b6-c81dbd4623b9'	System	21 Aug 2020 21:24:25
User entered '95.0'	System	21 Aug 2020 21:24:25

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:18', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '5eec0995-9db5-493e-99b6-c81dbd4623b9'	System	21 Aug 2020 21:24:25
User entered 'No (N)'	System	21 Aug 2020 21:24:25

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:22', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '5eec0995-9db5-493e-99b6-c81dbd4623b9'	System	21 Aug 2020 21:24:25
User entered '21 Aug 2020 14:24'	System	21 Aug 2020 21:24:25

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 7'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:16
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:10:06', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e54c8a72-b108-4e63-b855-3e267842bf91'	System	22 Aug 2020 21:10:20
User entered 'Yes (Y)'	System	22 Aug 2020 21:10:20

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:16
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:10:11', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e54c8a72-b108-4e63-b855-3e267842bf91'	System	22 Aug 2020 21:10:20
User entered '96.0'	System	22 Aug 2020 21:10:20

US3192291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:10:14', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e54c8a72-b108-4e63-b855-3e267842bf91'	System	22 Aug 2020 21:10:20
User entered 'No (N)'	System	22 Aug 2020 21:10:20

US3192291
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:10:18', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e54c8a72-b108-4e63-b855-3e267842bf91'	System	22 Aug 2020 21:10:20
User entered '22 Aug 2020 14:10'	System	22 Aug 2020 21:10:20

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

FDA-CBER-2022-1614-0408264

Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:22:07

Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

FDA-CBER-2022-1614-0408270

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Aug 2020 10:40'	System	16 Aug 2020 17:22:07

Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Aug 2020 13:10'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:05:41', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2ed7dc72-3258-48af-8388-b190e1441e57'	System	16 Aug 2020 21:06:12
User entered 'None (1)'	System	16 Aug 2020 21:06:12

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:05:52', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2ed7dc72-3258-48af-8388-b190e1441e57'	System	16 Aug 2020 21:06:12
User entered 'No (N)'	System	16 Aug 2020 21:06:12

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:05:56', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2ed7dc72-3258-48af-8388-b190e1441e57'	System	16 Aug 2020 21:06:12
User entered 'No (N)'	System	16 Aug 2020 21:06:12

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:06:03', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2ed7dc72-3258-48af-8388-b190e1441e57'	System	16 Aug 2020 21:06:12
User entered 'None (1)'	System	16 Aug 2020 21:06:12

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:06:10', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2ed7dc72-3258-48af-8388-b190e1441e57'	System	16 Aug 2020 21:06:12
User entered '16 Aug 2020 14:06'	System	16 Aug 2020 21:06:12

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Aug 2020 14:05'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 2'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:30:26', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '274dc2a5-11be-4efd-a204-21e25c2961a4'	System	18 Aug 2020 00:30:54
User entered 'None (1)'	System	18 Aug 2020 00:30:54

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:30:29', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '274dc2a5-11be-4efd-a204-21e25c2961a4'	System	18 Aug 2020 00:30:54
User entered 'No (N)'	System	18 Aug 2020 00:30:54

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:30:37', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '274dc2a5-11be-4efd-a204-21e25c2961a4'	System	18 Aug 2020 00:30:54
User entered 'No (N)'	System	18 Aug 2020 00:30:54

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:30:43', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '274dc2a5-11be-4efd-a204-21e25c2961a4'	System	18 Aug 2020 00:30:54
User entered 'None (1)'	System	18 Aug 2020 00:30:54

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:30:50', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '274dc2a5-11be-4efd-a204-21e25c2961a4'	System	18 Aug 2020 00:30:54
User entered '17 Aug 2020 17:30'	System	18 Aug 2020 00:30:54

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 3'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:12', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '331ea669-f338-4c62-aad0-42c3935f9faa'	System	18 Aug 2020 20:46:29
User entered 'None (1)'	System	18 Aug 2020 20:46:29

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:16', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '331ea669-f338-4c62-aad0-42c3935f9faa'	System	18 Aug 2020 20:46:29
User entered 'No (N)'	System	18 Aug 2020 20:46:29

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '331ea669-f338-4c62-aad0-42c3935f9faa'	System	18 Aug 2020 20:46:29
User entered 'No (N)'	System	18 Aug 2020 20:46:29

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:22', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '331ea669-f338-4c62-aad0-42c3935f9faa'	System	18 Aug 2020 20:46:29
User entered 'None (1)'	System	18 Aug 2020 20:46:29

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:27', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '331ea669-f338-4c62-aad0-42c3935f9faa'	System	18 Aug 2020 20:46:29
User entered '18 Aug 2020 13:46'	System	18 Aug 2020 20:46:29

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 4'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:16
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:28:43', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '01c3d0bd-4259-49ef-a625-dd0e82692e1d'	System	20 Aug 2020 02:29:00
User entered 'None (1)'	System	20 Aug 2020 02:29:00

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:28:46', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '01c3d0bd-4259-49ef-a625-dd0e82692e1d'	System	20 Aug 2020 02:29:00
User entered 'No (N)'	System	20 Aug 2020 02:29:00

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:28:49', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '01c3d0bd-4259-49ef-a625-dd0e82692e1d'	System	20 Aug 2020 02:29:00
User entered 'No (N)'	System	20 Aug 2020 02:29:00

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:28:53', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '01c3d0bd-4259-49ef-a625-dd0e82692e1d'	System	20 Aug 2020 02:29:00
User entered 'None (1)'	System	20 Aug 2020 02:29:00

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:28:59', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '01c3d0bd-4259-49ef-a625-dd0e82692e1d'	System	20 Aug 2020 02:29:00
User entered '19 Aug 2020 19:28'	System	20 Aug 2020 02:29:00

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 5'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:31:33', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd62f0126-8aac-4709-a0b1-a38e91759dfa'	System	21 Aug 2020 03:31:55
User entered 'None (1)'	System	21 Aug 2020 03:31:55

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:16
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:31:36', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd62f0126-8aac-4709-a0b1-a38e91759dfa'	System	21 Aug 2020 03:31:55
User entered 'No (N)'	System	21 Aug 2020 03:31:55

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:31:40', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd62f0126-8aac-4709-a0b1-a38e91759dfa'	System	21 Aug 2020 03:31:55
User entered 'No (N)'	System	21 Aug 2020 03:31:55

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:31:44', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd62f0126-8aac-4709-a0b1-a38e91759dfa'	System	21 Aug 2020 03:31:55
User entered 'None (1)'	System	21 Aug 2020 03:31:55

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:31:53', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd62f0126-8aac-4709-a0b1-a38e91759dfa'	System	21 Aug 2020 03:31:55
User entered '20 Aug 2020 20:31'	System	21 Aug 2020 03:31:55

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 6'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:27', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '61b7400b-2143-4b69-9a1b-4c58a2c95193'	System	21 Aug 2020 21:24:40
User entered 'None (1)'	System	21 Aug 2020 21:24:40

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:29', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '61b7400b-2143-4b69-9a1b-4c58a2c95193'	System	21 Aug 2020 21:24:40
User entered 'No (N)'	System	21 Aug 2020 21:24:40

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:32', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '61b7400b-2143-4b69-9a1b-4c58a2c95193'	System	21 Aug 2020 21:24:40
User entered 'No (N)'	System	21 Aug 2020 21:24:40

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:34', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '61b7400b-2143-4b69-9a1b-4c58a2c95193'	System	21 Aug 2020 21:24:40
User entered 'None (1)'	System	21 Aug 2020 21:24:40

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:37', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '61b7400b-2143-4b69-9a1b-4c58a2c95193'	System	21 Aug 2020 21:24:40
User entered '21 Aug 2020 14:24'	System	21 Aug 2020 21:24:40

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 7'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:10:35', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'ef2eaa8e-4b4b-4eec-b36a-71b80dd6d39e'	System	22 Aug 2020 21:10:49
User entered 'None (1)'	System	22 Aug 2020 21:10:49

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:10:25', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'ef2eaa8e-4b4b-4eec-b36a-71b80dd6d39e'	System	22 Aug 2020 21:10:49
User entered 'No (N)'	System	22 Aug 2020 21:10:49

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:10:28', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'ef2eaa8e-4b4b-4eec-b36a-71b80dd6d39e'	System	22 Aug 2020 21:10:49
User entered 'No (N)'	System	22 Aug 2020 21:10:49

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:10:30', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'ef2eaa8e-4b4b-4eec-b36a-71b80dd6d39e'	System	22 Aug 2020 21:10:49
User entered 'None (1)'	System	22 Aug 2020 21:10:49

US3192291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:16

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:10:45', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'ef2eaa8e-4b4b-4eec-b36a-71b80dd6d39e'	System	22 Aug 2020 21:10:49
User entered '22 Aug 2020 14:10'	System	22 Aug 2020 21:10:49

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Aug 2020 10:40'	System	16 Aug 2020 17:22:07

FDA-CBER-2022-1614-0408341

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Aug 2020 13:10'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:06:33', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'de395c92-ba04-486e-a7c2-c18b32b712f2'	System	16 Aug 2020 21:07:10
User entered 'None (0)'	System	16 Aug 2020 21:07:10

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:06:36', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'de395c92-ba04-486e-a7c2-c18b32b712f2'	System	16 Aug 2020 21:07:10
User entered 'None (0)'	System	16 Aug 2020 21:07:10

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:06:39', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'de395c92-ba04-486e-a7c2-c18b32b712f2'	System	16 Aug 2020 21:07:10
User entered 'None (0)'	System	16 Aug 2020 21:07:10

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:06:42', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'de395c92-ba04-486e-a7c2-c18b32b712f2'	System	16 Aug 2020 21:07:10
User entered 'None (0)'	System	16 Aug 2020 21:07:10

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:06:45', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'de395c92-ba04-486e-a7c2-c18b32b712f2'	System	16 Aug 2020 21:07:10
User entered 'None (0)'	System	16 Aug 2020 21:07:10

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:06:49', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'de395c92-ba04-486e-a7c2-c18b32b712f2'	System	16 Aug 2020 21:07:10
User entered 'None (0)'	System	16 Aug 2020 21:07:10

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:06:59', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'de395c92-ba04-486e-a7c2-c18b32b712f2'	System	16 Aug 2020 21:07:10
User entered 'No (N)'	System	16 Aug 2020 21:07:10

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-16T14:07:07', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'de395c92-ba04-486e-a7c2-c18b32b712f2'	System	16 Aug 2020 21:07:10
User entered '16 Aug 2020 14:07'	System	16 Aug 2020 21:07:10

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Aug 2020 14:05'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 2'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:30:55', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a0d62283-f57b-4222-93c2-6266b24d05b1'	System	18 Aug 2020 00:31:37
User entered 'None (0)'	System	18 Aug 2020 00:31:37

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:30:58', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a0d62283-f57b-4222-93c2-6266b24d05b1'	System	18 Aug 2020 00:31:37
User entered 'None (0)'	System	18 Aug 2020 00:31:37

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:31:02', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a0d62283-f57b-4222-93c2-6266b24d05b1'	System	18 Aug 2020 00:31:37
User entered 'None (0)'	System	18 Aug 2020 00:31:37

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:31:08', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a0d62283-f57b-4222-93c2-6266b24d05b1'	System	18 Aug 2020 00:31:37
User entered 'None (0)'	System	18 Aug 2020 00:31:37

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:31:13', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a0d62283-f57b-4222-93c2-6266b24d05b1'	System	18 Aug 2020 00:31:37
User entered 'None (0)'	System	18 Aug 2020 00:31:37

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:31:15', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a0d62283-f57b-4222-93c2-6266b24d05b1'	System	18 Aug 2020 00:31:37
User entered 'None (0)'	System	18 Aug 2020 00:31:37

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:31:22', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a0d62283-f57b-4222-93c2-6266b24d05b1'	System	18 Aug 2020 00:31:37
User entered 'No (N)'	System	18 Aug 2020 00:31:37

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-17T17:31:33', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a0d62283-f57b-4222-93c2-6266b24d05b1'	System	18 Aug 2020 00:31:37
User entered '17 Aug 2020 17:31'	System	18 Aug 2020 00:31:37

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 3'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:33', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '18115baa-faef-4eec-8f41-0245dea1ad15'	System	18 Aug 2020 20:46:58
User entered 'None (0)'	System	18 Aug 2020 20:46:58

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:35', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '18115baa-faef-4eec-8f41-0245dea1ad15'	System	18 Aug 2020 20:46:58
User entered 'None (0)'	System	18 Aug 2020 20:46:58

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:38', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '18115baa-faef-4eec-8f41-0245dea1ad15'	System	18 Aug 2020 20:46:58
User entered 'None (0)'	System	18 Aug 2020 20:46:58

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:41', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '18115baa-faef-4eec-8f41-0245dea1ad15'	System	18 Aug 2020 20:46:58
User entered 'None (0)'	System	18 Aug 2020 20:46:58

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:43', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '18115baa-faef-4eec-8f41-0245dea1ad15'	System	18 Aug 2020 20:46:58
User entered 'None (0)'	System	18 Aug 2020 20:46:58

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:48', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '18115baa-faef-4eec-8f41-0245dea1ad15'	System	18 Aug 2020 20:46:58
User entered 'None (0)'	System	18 Aug 2020 20:46:58

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:52', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '18115baa-faef-4eec-8f41-0245dea1ad15'	System	18 Aug 2020 20:46:58
User entered 'No (N)'	System	18 Aug 2020 20:46:58

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-18T13:46:55', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '18115baa-faef-4eec-8f41-0245dea1ad15'	System	18 Aug 2020 20:46:58
User entered '18 Aug 2020 13:46'	System	18 Aug 2020 20:46:58

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 4'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:29:07', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f06f450-c75a-4b7a-8b18-87512726cd11'	System	20 Aug 2020 02:29:42
User entered 'None (0)'	System	20 Aug 2020 02:29:42

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:29:10', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f06f450-c75a-4b7a-8b18-87512726cd11'	System	20 Aug 2020 02:29:42
User entered 'None (0)'	System	20 Aug 2020 02:29:42

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:29:13', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f06f450-c75a-4b7a-8b18-87512726cd11'	System	20 Aug 2020 02:29:42
User entered 'None (0)'	System	20 Aug 2020 02:29:42

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:29:16', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f06f450-c75a-4b7a-8b18-87512726cd11'	System	20 Aug 2020 02:29:42
User entered 'None (0)'	System	20 Aug 2020 02:29:42

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:29:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f06f450-c75a-4b7a-8b18-87512726cd11'	System	20 Aug 2020 02:29:42
User entered 'None (0)'	System	20 Aug 2020 02:29:42

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:29:23', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f06f450-c75a-4b7a-8b18-87512726cd11'	System	20 Aug 2020 02:29:42
User entered 'None (0)'	System	20 Aug 2020 02:29:42

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:29:29', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f06f450-c75a-4b7a-8b18-87512726cd11'	System	20 Aug 2020 02:29:42
User entered 'No (N)'	System	20 Aug 2020 02:29:42

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-19T19:29:38', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f06f450-c75a-4b7a-8b18-87512726cd11'	System	20 Aug 2020 02:29:42
User entered '19 Aug 2020 19:29'	System	20 Aug 2020 02:29:42

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 5'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:32:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e857936c-8ca7-4e44-9b66-6e6bfc5f475d'	System	21 Aug 2020 03:43:42
User entered 'None (0)'	System	21 Aug 2020 03:43:42

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:32:02', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e857936c-8ca7-4e44-9b66-6e6bfc5f475d'	System	21 Aug 2020 03:43:42
User entered 'None (0)'	System	21 Aug 2020 03:43:42

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:32:05', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e857936c-8ca7-4e44-9b66-6e6bfc5f475d'	System	21 Aug 2020 03:43:42
User entered 'None (0)'	System	21 Aug 2020 03:43:42

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:32:12', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e857936c-8ca7-4e44-9b66-6e6bfc5f475d'	System	21 Aug 2020 03:43:42
User entered 'None (0)'	System	21 Aug 2020 03:43:42

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:32:16', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e857936c-8ca7-4e44-9b66-6e6bfc5f475d'	System	21 Aug 2020 03:43:42
User entered 'None (0)'	System	21 Aug 2020 03:43:42

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:32:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e857936c-8ca7-4e44-9b66-6e6bfc5f475d'	System	21 Aug 2020 03:43:42
User entered 'None (0)'	System	21 Aug 2020 03:43:42

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:43:31', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e857936c-8ca7-4e44-9b66-6e6bfc5f475d'	System	21 Aug 2020 03:43:42
User entered 'No (N)'	System	21 Aug 2020 03:43:42

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-20T20:43:40', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e857936c-8ca7-4e44-9b66-6e6bfc5f475d'	System	21 Aug 2020 03:43:42
User entered '20 Aug 2020 20:43'	System	21 Aug 2020 03:43:42

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

FDA-CBER-2022-1614-0408397

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 6'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:42', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'bc7db497-76d6-4e7e-bc26-6bd0b7e5bdc9'	System	21 Aug 2020 21:25:05
User entered 'None (0)'	System	21 Aug 2020 21:25:05

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:43', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'bc7db497-76d6-4e7e-bc26-6bd0b7e5bdc9'	System	21 Aug 2020 21:25:05
User entered 'None (0)'	System	21 Aug 2020 21:25:05

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:45', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'bc7db497-76d6-4e7e-bc26-6bd0b7e5bdc9'	System	21 Aug 2020 21:25:05
User entered 'None (0)'	System	21 Aug 2020 21:25:05

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:48', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'bc7db497-76d6-4e7e-bc26-6bd0b7e5bdc9'	System	21 Aug 2020 21:25:05
User entered 'None (0)'	System	21 Aug 2020 21:25:05

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:50', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'bc7db497-76d6-4e7e-bc26-6bd0b7e5bdc9'	System	21 Aug 2020 21:25:05
User entered 'None (0)'	System	21 Aug 2020 21:25:05

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:52', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'bc7db497-76d6-4e7e-bc26-6bd0b7e5bdc9'	System	21 Aug 2020 21:25:05
User entered 'None (0)'	System	21 Aug 2020 21:25:05

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:24:56', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'bc7db497-76d6-4e7e-bc26-6bd0b7e5bdc9'	System	21 Aug 2020 21:25:05
User entered 'No (N)'	System	21 Aug 2020 21:25:05

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-21T14:25:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'bc7db497-76d6-4e7e-bc26-6bd0b7e5bdc9'	System	21 Aug 2020 21:25:05
User entered '21 Aug 2020 14:25'	System	21 Aug 2020 21:25:05

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 7'	System	16 Aug 2020 17:22:07

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:11:06', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'da6fa6e3-0951-4f1a-84c5-857ffa5a4da1'	System	22 Aug 2020 21:11:22
User entered 'None (0)'	System	22 Aug 2020 21:11:22

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:11:08', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'da6fa6e3-0951-4f1a-84c5-857ffa5a4da1'	System	22 Aug 2020 21:11:22
User entered 'None (0)'	System	22 Aug 2020 21:11:22

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:11:10', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'da6fa6e3-0951-4f1a-84c5-857ffa5a4da1'	System	22 Aug 2020 21:11:22
User entered 'None (0)'	System	22 Aug 2020 21:11:22

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:11:12', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'da6fa6e3-0951-4f1a-84c5-857ffa5a4da1'	System	22 Aug 2020 21:11:22
User entered 'None (0)'	System	22 Aug 2020 21:11:22

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:11:13', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'da6fa6e3-0951-4f1a-84c5-857ffa5a4da1'	System	22 Aug 2020 21:11:22
User entered 'None (0)'	System	22 Aug 2020 21:11:22

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:11:15', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'da6fa6e3-0951-4f1a-84c5-857ffa5a4da1'	System	22 Aug 2020 21:11:22
User entered 'None (0)'	System	22 Aug 2020 21:11:22

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:11:17', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'da6fa6e3-0951-4f1a-84c5-857ffa5a4da1'	System	22 Aug 2020 21:11:22
User entered 'No (N)'	System	22 Aug 2020 21:11:22

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-08-22T14:11:20', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'da6fa6e3-0951-4f1a-84c5-857ffa5a4da1'	System	22 Aug 2020 21:11:22
User entered '22 Aug 2020 14:11'	System	22 Aug 2020 21:11:22

US3192291
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:22:07

US3192291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:20:10

US3192291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '25 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:20:10

US3192291
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Contact Made (CONTACT MADE)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:20:10

Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:20:10

FDA-CBER-2022-1614-0408423

US3192291
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:20:17

US3192291
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '1'	System	10 Sep 2020 20:20:17

US3192291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:48:01
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:20:42

FDA-CBER-2022-1614-0408426

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:48:01
User entered '02 Sep 2020'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:20:42

FDA-CBER-2022-1614-0408427

US3192291
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:48:01
User entered 'Contact Made (CONTACT MADE)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:20:42

US3192291
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:48:01
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:20:42

US3192291
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:48:01
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:20:50

US3192291
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '1'	System	10 Sep 2020 20:20:50

US3192291
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:21:10

US3192291
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '08 Sep 2020'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:21:10

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Contact Made (CONTACT MADE)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:21:10

FDA-CBER-2022-1614-0408434

US3192291
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:21:10

US3192291

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:21:19

US3192291
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '1'	System	10 Sep 2020 20:21:19

US3192291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 06:48:14
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'edc has been updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	24 Jan 2021 16:32:06
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:37:54
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:36:41

US3192291
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 07:55:36
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'Updated' (Site from DM).	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:18:07
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:52:26
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 18:42:23
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Visit 2 still falls within the window of 10 Sep 2020 through 20 Sep 2020 according to calendar in source.' (Site from System).	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:38:22

US3192291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Sep 2020 16:36:41
User entered '12 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:36:41

US3192291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User entered 'Clinic (Clinic)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:36:41

US3192291
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'VISIT2'	System	14 Sep 2020 16:36:41

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User accepted default value 'Pre-Dose (PREDOSE)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:11

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:11

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '12 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:11

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '11:07'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:11

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '12 Sep 2020 11:07'	System	14 Sep 2020 16:39:11

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '97.0' F	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:11

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Oral (Oral)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:11

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:11

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '70'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:11

FDA-CBER-2022-1614-0408451

US3192291
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'bpm'	System	14 Sep 2020 16:39:11

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '12'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:11

FDA-CBER-2022-1614-0408453

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'breaths/min'	System	14 Sep 2020 16:39:11

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '149'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:11

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'mmHg'	System	14 Sep 2020 16:39:11

US3192291
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '85'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:11

US3192291
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'mmHg'	System	14 Sep 2020 16:39:11

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User accepted default value 'Post-Dose (POSTDOSE)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:52

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:16
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '12 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:52

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '12:39'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:52

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '12 Sep 2020 12:39'	System	14 Sep 2020 16:39:52

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '98.4' F	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:52

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Oral (Oral)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:52

US3192291
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:16
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:52

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '69'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:52

US3192291
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:16
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'bpm'	System	14 Sep 2020 16:39:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '12'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:52

FDA-CBER-2022-1614-0408469

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'breaths/min'	System	14 Sep 2020 16:39:52

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '145'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:52

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:16
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'mmHg'	System	14 Sep 2020 16:39:52

FDA-CBER-2022-1614-0408472

US3192291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '97'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:39:52

US3192291
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'mmHg'	System	14 Sep 2020 16:39:52

Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:16
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:40:01

US3192291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '12 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:40:01

US3192291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	12 Sep 2020 19:15:59

US3192291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Zoe Sesma (b) (4) (b) (4)	12 Sep 2020 19:15:59

US3192291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

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)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Zoe Sesma (b) (4) (b) (4)	12 Sep 2020 19:15:59

US3192291
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'MRNA-1273 OR PLACEBO'	System	12 Sep 2020 19:15:59

US3192291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '12 Sep 2020'	Zoe Sesma (b) (4) (b) (4)	12 Sep 2020 19:15:59

US3192291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '12:09'	Zoe Sesma (b) (4) (b) (4)	12 Sep 2020 19:15:59

US3192291
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '12 Sep 2020 12:09'	System	12 Sep 2020 19:15:59

US3192291
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Right Arm (RIGHT ARM)'	Zoe Sesma (b) (4) (b) (4)	12 Sep 2020 19:15:59

US3192291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'ONCE'	System	12 Sep 2020 19:15:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'INTRAMUSCULAR'	System	12 Sep 2020 19:15:59

US3192291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:37:44
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:37:36
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:41:18

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '12 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:41:18

US3192291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '11:47'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:41:18

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '12 Sep 2020 11:47'	System	14 Sep 2020 16:41:18

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '12 Sep 2020'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:41:42

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:40:16
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:41:42

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:40:16

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:41:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '11:52'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:41:42

FDA-CBER-2022-1614-0408494

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '12 Sep 2020 11:52'	System	14 Sep 2020 16:41:42

US3192291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:16

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:41:46

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:40:16
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:41:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:41:46

FDA-CBER-2022-1614-0408498

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered empty.	System	14 Sep 2020 16:41:46

FDA-CBER-2022-1614-0408499

US3192291
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	14 Sep 2020 16:41:50

US3192291
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '1'	System	14 Sep 2020 16:41:50

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:29:46', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '760c5045-1295-479b-ac82-528a9fcfaea1'	System	12 Sep 2020 19:30:14
User entered 'Yes (Y)'	System	12 Sep 2020 19:30:14

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:29:52', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '760c5045-1295-479b-ac82-528a9fcfaea1'	System	12 Sep 2020 19:30:14
User entered '98.4'	System	12 Sep 2020 19:30:14

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:29:57', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '760c5045-1295-479b-ac82-528a9fcfaea1'	System	12 Sep 2020 19:30:14
User entered 'No (N)'	System	12 Sep 2020 19:30:14

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:30:12', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '760c5045-1295-479b-ac82-528a9fcfaea1'	System	12 Sep 2020 19:30:14
User entered '12 Sep 2020 12:30'	System	12 Sep 2020 19:30:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '12 Sep 2020 12:29'	System	12 Sep 2020 19:15:59

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '12 Sep 2020 14:59'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408508

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:01:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1c239aba-16ff-46a8-931b-8ad98dcc4d47'	System	13 Sep 2020 03:01:37
User entered 'Yes (Y)'	System	13 Sep 2020 03:01:37

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:01:24', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1c239aba-16ff-46a8-931b-8ad98dcc4d47'	System	13 Sep 2020 03:01:37
User entered '95.2'	System	13 Sep 2020 03:01:37

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:01:28', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1c239aba-16ff-46a8-931b-8ad98dcc4d47'	System	13 Sep 2020 03:01:37
User entered 'No (N)'	System	13 Sep 2020 03:01:37

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:01:32', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1c239aba-16ff-46a8-931b-8ad98dcc4d47'	System	13 Sep 2020 03:01:37
User entered '12 Sep 2020 20:01'	System	13 Sep 2020 03:01:37

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '12 Sep 2020 15:54'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408514

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 2'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:33:07', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '58458eb8-ffc9-48aa-b795-348cdc1c8df1'	System	14 Sep 2020 02:33:37
User entered 'Yes (Y)'	System	14 Sep 2020 02:33:37

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:33:16', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '58458eb8-ffc9-48aa-b795-348cdc1c8df1'	System	14 Sep 2020 02:33:37
User entered '95.0'	System	14 Sep 2020 02:33:37

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:33:28', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '58458eb8-ffc9-48aa-b795-348cdc1c8df1'	System	14 Sep 2020 02:33:37
User entered 'No (N)'	System	14 Sep 2020 02:33:37

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:33:33', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '58458eb8-ffc9-48aa-b795-348cdc1c8df1'	System	14 Sep 2020 02:33:37
User entered '13 Sep 2020 19:33'	System	14 Sep 2020 02:33:37

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 3'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:16
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:07:43', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2a48774d-67b6-4eb8-a6d0-b6d4bf6a7ccf'	System	15 Sep 2020 02:08:07
User entered 'Yes (Y)'	System	15 Sep 2020 02:08:07

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:07:51', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2a48774d-67b6-4eb8-a6d0-b6d4bf6a7ccf'	System	15 Sep 2020 02:08:07
User entered '96.0'	System	15 Sep 2020 02:08:07

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:07:55', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2a48774d-67b6-4eb8-a6d0-b6d4bf6a7ccf'	System	15 Sep 2020 02:08:07
User entered 'No (N)'	System	15 Sep 2020 02:08:07

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2a48774d-67b6-4eb8-a6d0-b6d4bf6a7ccf'	System	15 Sep 2020 02:08:07
User entered '14 Sep 2020 19:08'	System	15 Sep 2020 02:08:07

Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408529

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 4'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:16
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:19:44', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1b774081-d1c2-4b94-83cb-8712c05e57f6'	System	16 Sep 2020 15:19:59
User entered 'Yes (Y)'	System	16 Sep 2020 15:19:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:19:51', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1b774081-d1c2-4b94-83cb-8712c05e57f6'	System	16 Sep 2020 15:19:59
User entered '97.4'	System	16 Sep 2020 15:19:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:19:54', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1b774081-d1c2-4b94-83cb-8712c05e57f6'	System	16 Sep 2020 15:19:59
User entered 'No (N)'	System	16 Sep 2020 15:19:59

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:19:57', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1b774081-d1c2-4b94-83cb-8712c05e57f6'	System	16 Sep 2020 15:19:59
User entered '16 Sep 2020 08:19'	System	16 Sep 2020 15:19:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 5'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408537

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:03:20', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '436c175b-6542-4829-84cb-d2222d4e6e9d'	System	17 Sep 2020 04:03:43
User entered 'Yes (Y)'	System	17 Sep 2020 04:03:43

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:03:28', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '436c175b-6542-4829-84cb-d2222d4e6e9d'	System	17 Sep 2020 04:03:43
User entered '96.0'	System	17 Sep 2020 04:03:43

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:03:34', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '436c175b-6542-4829-84cb-d2222d4e6e9d'	System	17 Sep 2020 04:03:43
User entered 'No (N)'	System	17 Sep 2020 04:03:43

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:40:16

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:03:38', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '436c175b-6542-4829-84cb-d2222d4e6e9d'	System	17 Sep 2020 04:03:43
User entered '16 Sep 2020 21:03'	System	17 Sep 2020 04:03:43

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 6'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:01', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b20d71c7-10ab-4841-82fd-d03b299da8db'	System	18 Sep 2020 00:41:26
User entered 'Yes (Y)'	System	18 Sep 2020 00:41:26

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:40:53', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b20d71c7-10ab-4841-82fd-d03b299da8db'	System	18 Sep 2020 00:41:26
User entered '97.4'	System	18 Sep 2020 00:41:26

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:40:56', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b20d71c7-10ab-4841-82fd-d03b299da8db'	System	18 Sep 2020 00:41:26
User entered 'No (N)'	System	18 Sep 2020 00:41:26

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:22', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b20d71c7-10ab-4841-82fd-d03b299da8db'	System	18 Sep 2020 00:41:26
User entered '17 Sep 2020 17:41'	System	18 Sep 2020 00:41:26

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 7'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:53:32', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '66fe24d6-b3a6-4762-8d6c-67c700012f7d'	System	19 Sep 2020 05:54:09
User entered 'Yes (Y)'	System	19 Sep 2020 05:54:09

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:53:58', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '66fe24d6-b3a6-4762-8d6c-67c700012f7d'	System	19 Sep 2020 05:54:09
User entered '96.2'	System	19 Sep 2020 05:54:09

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:16

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:01', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '66fe24d6-b3a6-4762-8d6c-67c700012f7d'	System	19 Sep 2020 05:54:09
User entered 'No (N)'	System	19 Sep 2020 05:54:09

US3192291
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:05', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '66fe24d6-b3a6-4762-8d6c-67c700012f7d'	System	19 Sep 2020 05:54:09
User entered '18 Sep 2020 22:54'	System	19 Sep 2020 05:54:09

Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408557

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:30:41', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '048be3bb-01f1-45fb-9874-ea973ffad8f6'	System	12 Sep 2020 19:30:58
User entered 'None (1)'	System	12 Sep 2020 19:30:58

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:30:44', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '048be3bb-01f1-45fb-9874-ea973ffad8f6'	System	12 Sep 2020 19:30:58
User entered 'No (N)'	System	12 Sep 2020 19:30:58

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:30:47', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '048be3bb-01f1-45fb-9874-ea973ffad8f6'	System	12 Sep 2020 19:30:58
User entered 'No (N)'	System	12 Sep 2020 19:30:58

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:30:50', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '048be3bb-01f1-45fb-9874-ea973ffad8f6'	System	12 Sep 2020 19:30:58
User entered 'None (1)'	System	12 Sep 2020 19:30:58

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:30:54', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '048be3bb-01f1-45fb-9874-ea973ffad8f6'	System	12 Sep 2020 19:30:58
User entered '12 Sep 2020 12:30'	System	12 Sep 2020 19:30:58

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '12 Sep 2020 12:29'	System	12 Sep 2020 19:15:59

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '12 Sep 2020 14:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:01:36', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f8c3a9d-7b52-4d39-bd20-f999836ecd45'	System	13 Sep 2020 03:01:49
User entered 'None (1)'	System	13 Sep 2020 03:01:49

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:01:39', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f8c3a9d-7b52-4d39-bd20-f999836ecd45'	System	13 Sep 2020 03:01:49
User entered 'No (N)'	System	13 Sep 2020 03:01:49

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:01:42', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f8c3a9d-7b52-4d39-bd20-f999836ecd45'	System	13 Sep 2020 03:01:49
User entered 'No (N)'	System	13 Sep 2020 03:01:49

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:01:45', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f8c3a9d-7b52-4d39-bd20-f999836ecd45'	System	13 Sep 2020 03:01:49
User entered 'None (1)'	System	13 Sep 2020 03:01:49

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:01:48', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0f8c3a9d-7b52-4d39-bd20-f999836ecd45'	System	13 Sep 2020 03:01:49
User entered '12 Sep 2020 20:01'	System	13 Sep 2020 03:01:49

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '12 Sep 2020 15:54'	System	12 Sep 2020 19:15:59

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 2'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:33:41', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e057477c-c085-4555-9074-a602875cd828'	System	14 Sep 2020 02:34:02
User entered 'None (1)'	System	14 Sep 2020 02:34:02

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:33:44', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e057477c-c085-4555-9074-a602875cd828'	System	14 Sep 2020 02:34:02
User entered 'No (N)'	System	14 Sep 2020 02:34:02

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:33:47', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e057477c-c085-4555-9074-a602875cd828'	System	14 Sep 2020 02:34:02
User entered 'No (N)'	System	14 Sep 2020 02:34:02

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:33:52', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e057477c-c085-4555-9074-a602875cd828'	System	14 Sep 2020 02:34:02
User entered 'None (1)'	System	14 Sep 2020 02:34:02

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:33:58', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e057477c-c085-4555-9074-a602875cd828'	System	14 Sep 2020 02:34:02
User entered '13 Sep 2020 19:33'	System	14 Sep 2020 02:34:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408580

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408581

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 3'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:05', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '7311fffc-9cc3-4e47-8ea1-57aecc610205'	System	15 Sep 2020 02:08:19
User entered 'None (1)'	System	15 Sep 2020 02:08:19

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:07', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '7311fffc-9cc3-4e47-8ea1-57aecc610205'	System	15 Sep 2020 02:08:19
User entered 'No (N)'	System	15 Sep 2020 02:08:19

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:10', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '7311fffc-9cc3-4e47-8ea1-57aecc610205'	System	15 Sep 2020 02:08:19
User entered 'No (N)'	System	15 Sep 2020 02:08:19

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:12', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '7311fffc-9cc3-4e47-8ea1-57aecc610205'	System	15 Sep 2020 02:08:19
User entered 'None (1)'	System	15 Sep 2020 02:08:19

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:15', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '7311fffc-9cc3-4e47-8ea1-57aecc610205'	System	15 Sep 2020 02:08:19
User entered '14 Sep 2020 19:08'	System	15 Sep 2020 02:08:19

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408588

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 4'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:04', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1c726c53-66ff-46f5-b309-34273234fe81'	System	16 Sep 2020 15:20:21
User entered 'None (1)'	System	16 Sep 2020 15:20:21

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:06', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1c726c53-66ff-46f5-b309-34273234fe81'	System	16 Sep 2020 15:20:21
User entered 'No (N)'	System	16 Sep 2020 15:20:21

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:10', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1c726c53-66ff-46f5-b309-34273234fe81'	System	16 Sep 2020 15:20:21
User entered 'No (N)'	System	16 Sep 2020 15:20:21

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:12', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1c726c53-66ff-46f5-b309-34273234fe81'	System	16 Sep 2020 15:20:21
User entered 'None (1)'	System	16 Sep 2020 15:20:21

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:16

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:14', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1c726c53-66ff-46f5-b309-34273234fe81'	System	16 Sep 2020 15:20:21
User entered '16 Sep 2020 08:20'	System	16 Sep 2020 15:20:21

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 5'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:03:43', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd625ae9d-fe03-414e-bdce-fa1385cdb333'	System	17 Sep 2020 04:04:14
User entered 'None (1)'	System	17 Sep 2020 04:04:14

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:03:55', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd625ae9d-fe03-414e-bdce-fa1385cdb333'	System	17 Sep 2020 04:04:14
User entered 'No (N)'	System	17 Sep 2020 04:04:14

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:03:59', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd625ae9d-fe03-414e-bdce-fa1385cdb333'	System	17 Sep 2020 04:04:14
User entered 'No (N)'	System	17 Sep 2020 04:04:14

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:04:04', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd625ae9d-fe03-414e-bdce-fa1385cdb333'	System	17 Sep 2020 04:04:14
User entered 'None (1)'	System	17 Sep 2020 04:04:14

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:16

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:04:10', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd625ae9d-fe03-414e-bdce-fa1385cdb333'	System	17 Sep 2020 04:04:14
User entered '16 Sep 2020 21:04'	System	17 Sep 2020 04:04:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408604

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 6'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:29', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f647f70e-81f6-4658-943c-6db39641b24a'	System	18 Sep 2020 00:41:44
User entered 'None (1)'	System	18 Sep 2020 00:41:44

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:34', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f647f70e-81f6-4658-943c-6db39641b24a'	System	18 Sep 2020 00:41:44
User entered 'No (N)'	System	18 Sep 2020 00:41:44

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:37', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f647f70e-81f6-4658-943c-6db39641b24a'	System	18 Sep 2020 00:41:44
User entered 'No (N)'	System	18 Sep 2020 00:41:44

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:39', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f647f70e-81f6-4658-943c-6db39641b24a'	System	18 Sep 2020 00:41:44
User entered 'None (1)'	System	18 Sep 2020 00:41:44

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:16

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:42', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f647f70e-81f6-4658-943c-6db39641b24a'	System	18 Sep 2020 00:41:44
User entered '17 Sep 2020 17:41'	System	18 Sep 2020 00:41:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 7'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:09', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '655a3c83-eac4-4671-a8eb-c833f2ba528f'	System	19 Sep 2020 05:54:26
User entered 'None (1)'	System	19 Sep 2020 05:54:26

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:12', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '655a3c83-eac4-4671-a8eb-c833f2ba528f'	System	19 Sep 2020 05:54:26
User entered 'No (N)'	System	19 Sep 2020 05:54:26

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:16
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:15', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '655a3c83-eac4-4671-a8eb-c833f2ba528f'	System	19 Sep 2020 05:54:26
User entered 'No (N)'	System	19 Sep 2020 05:54:26

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:18', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '655a3c83-eac4-4671-a8eb-c833f2ba528f'	System	19 Sep 2020 05:54:26
User entered 'None (1)'	System	19 Sep 2020 05:54:26

US3192291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:16

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:24', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '655a3c83-eac4-4671-a8eb-c833f2ba528f'	System	19 Sep 2020 05:54:26
User entered '18 Sep 2020 22:54'	System	19 Sep 2020 05:54:26

US3192291
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:16
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:30:58', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f65359f5-d936-4e24-ad42-da0e1af03a5c'	System	12 Sep 2020 19:31:19
User entered 'None (0)'	System	12 Sep 2020 19:31:19

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:31:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f65359f5-d936-4e24-ad42-da0e1af03a5c'	System	12 Sep 2020 19:31:19
User entered 'None (0)'	System	12 Sep 2020 19:31:19

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:31:02', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f65359f5-d936-4e24-ad42-da0e1af03a5c'	System	12 Sep 2020 19:31:19
User entered 'None (0)'	System	12 Sep 2020 19:31:19

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:31:05', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f65359f5-d936-4e24-ad42-da0e1af03a5c'	System	12 Sep 2020 19:31:19
User entered 'None (0)'	System	12 Sep 2020 19:31:19

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:31:07', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f65359f5-d936-4e24-ad42-da0e1af03a5c'	System	12 Sep 2020 19:31:19
User entered 'None (0)'	System	12 Sep 2020 19:31:19

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:31:08', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f65359f5-d936-4e24-ad42-da0e1af03a5c'	System	12 Sep 2020 19:31:19
User entered 'None (0)'	System	12 Sep 2020 19:31:19

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:31:12', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f65359f5-d936-4e24-ad42-da0e1af03a5c'	System	12 Sep 2020 19:31:19
User entered 'No (N)'	System	12 Sep 2020 19:31:19

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:40:16
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T12:31:15', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f65359f5-d936-4e24-ad42-da0e1af03a5c'	System	12 Sep 2020 19:31:19
User entered '12 Sep 2020 12:31'	System	12 Sep 2020 19:31:19

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '12 Sep 2020 12:29'	System	12 Sep 2020 19:15:59

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '12 Sep 2020 14:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T19:54:59', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '15f10a77-2c05-4d60-84e5-a80dfa136bfd'	System	13 Sep 2020 03:02:59
User entered 'None (0)'	System	13 Sep 2020 03:02:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T19:55:05', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '15f10a77-2c05-4d60-84e5-a80dfa136bfd'	System	13 Sep 2020 03:02:59
User entered 'No interference with activity (1)'	System	13 Sep 2020 03:02:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T19:55:08', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '15f10a77-2c05-4d60-84e5-a80dfa136bfd'	System	13 Sep 2020 03:02:59
User entered 'None (0)'	System	13 Sep 2020 03:02:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:02:04', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '15f10a77-2c05-4d60-84e5-a80dfa136bfd'	System	13 Sep 2020 03:02:59
User entered 'None (0)'	System	13 Sep 2020 03:02:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:02:08', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '15f10a77-2c05-4d60-84e5-a80dfa136bfd'	System	13 Sep 2020 03:02:59
User entered 'None (0)'	System	13 Sep 2020 03:02:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:02:10', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '15f10a77-2c05-4d60-84e5-a80dfa136bfd'	System	13 Sep 2020 03:02:59
User entered 'None (0)'	System	13 Sep 2020 03:02:59

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:02:23', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '15f10a77-2c05-4d60-84e5-a80dfa136bfd'	System	13 Sep 2020 03:02:59
User entered 'No (N)'	System	13 Sep 2020 03:02:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:40:16
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-12T20:02:54', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '15f10a77-2c05-4d60-84e5-a80dfa136bfd'	System	13 Sep 2020 03:02:59
User entered '12 Sep 2020 20:02'	System	13 Sep 2020 03:02:59

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '12 Sep 2020 15:54'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408642

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408643

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 2'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:34:05', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a7b15b8f-63ce-4260-b84c-6fc0dc44648f'	System	14 Sep 2020 02:34:38
User entered 'None (0)'	System	14 Sep 2020 02:34:38

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:34:11', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a7b15b8f-63ce-4260-b84c-6fc0dc44648f'	System	14 Sep 2020 02:34:38
User entered 'No interference with activity (1)'	System	14 Sep 2020 02:34:38

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:34:13', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a7b15b8f-63ce-4260-b84c-6fc0dc44648f'	System	14 Sep 2020 02:34:38
User entered 'None (0)'	System	14 Sep 2020 02:34:38

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:34:17', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a7b15b8f-63ce-4260-b84c-6fc0dc44648f'	System	14 Sep 2020 02:34:38
User entered 'None (0)'	System	14 Sep 2020 02:34:38

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:34:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a7b15b8f-63ce-4260-b84c-6fc0dc44648f'	System	14 Sep 2020 02:34:38
User entered 'None (0)'	System	14 Sep 2020 02:34:38

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:34:21', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a7b15b8f-63ce-4260-b84c-6fc0dc44648f'	System	14 Sep 2020 02:34:38
User entered 'None (0)'	System	14 Sep 2020 02:34:38

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:34:28', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a7b15b8f-63ce-4260-b84c-6fc0dc44648f'	System	14 Sep 2020 02:34:38
User entered 'No (N)'	System	14 Sep 2020 02:34:38

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-13T19:34:35', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a7b15b8f-63ce-4260-b84c-6fc0dc44648f'	System	14 Sep 2020 02:34:38
User entered '13 Sep 2020 19:34'	System	14 Sep 2020 02:34:38

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 3'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '32071ea2-2f7d-49d4-a70d-2f1a53b004c9'	System	15 Sep 2020 02:08:42
User entered 'None (0)'	System	15 Sep 2020 02:08:42

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:21', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '32071ea2-2f7d-49d4-a70d-2f1a53b004c9'	System	15 Sep 2020 02:08:42
User entered 'None (0)'	System	15 Sep 2020 02:08:42

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:23', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '32071ea2-2f7d-49d4-a70d-2f1a53b004c9'	System	15 Sep 2020 02:08:42
User entered 'None (0)'	System	15 Sep 2020 02:08:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:25', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '32071ea2-2f7d-49d4-a70d-2f1a53b004c9'	System	15 Sep 2020 02:08:42
User entered 'None (0)'	System	15 Sep 2020 02:08:42

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:27', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '32071ea2-2f7d-49d4-a70d-2f1a53b004c9'	System	15 Sep 2020 02:08:42
User entered 'None (0)'	System	15 Sep 2020 02:08:42

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:29', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '32071ea2-2f7d-49d4-a70d-2f1a53b004c9'	System	15 Sep 2020 02:08:42
User entered 'None (0)'	System	15 Sep 2020 02:08:42

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:37', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '32071ea2-2f7d-49d4-a70d-2f1a53b004c9'	System	15 Sep 2020 02:08:42
User entered 'No (N)'	System	15 Sep 2020 02:08:42

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-14T19:08:40', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '32071ea2-2f7d-49d4-a70d-2f1a53b004c9'	System	15 Sep 2020 02:08:42
User entered '14 Sep 2020 19:08'	System	15 Sep 2020 02:08:42

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 4'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '943591e3-b896-4da2-b3b1-3a2caf10a205'	System	16 Sep 2020 15:20:36
User entered 'None (0)'	System	16 Sep 2020 15:20:36

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:20', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '943591e3-b896-4da2-b3b1-3a2caf10a205'	System	16 Sep 2020 15:20:36
User entered 'None (0)'	System	16 Sep 2020 15:20:36

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:22', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '943591e3-b896-4da2-b3b1-3a2caf10a205'	System	16 Sep 2020 15:20:36
User entered 'None (0)'	System	16 Sep 2020 15:20:36

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:23', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '943591e3-b896-4da2-b3b1-3a2caf10a205'	System	16 Sep 2020 15:20:36
User entered 'None (0)'	System	16 Sep 2020 15:20:36

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:25', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '943591e3-b896-4da2-b3b1-3a2caf10a205'	System	16 Sep 2020 15:20:36
User entered 'None (0)'	System	16 Sep 2020 15:20:36

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:27', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '943591e3-b896-4da2-b3b1-3a2caf10a205'	System	16 Sep 2020 15:20:36
User entered 'None (0)'	System	16 Sep 2020 15:20:36

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:31', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '943591e3-b896-4da2-b3b1-3a2caf10a205'	System	16 Sep 2020 15:20:36
User entered 'No (N)'	System	16 Sep 2020 15:20:36

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T08:20:34', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '943591e3-b896-4da2-b3b1-3a2caf10a205'	System	16 Sep 2020 15:20:36
User entered '16 Sep 2020 08:20'	System	16 Sep 2020 15:20:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408675

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408676

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 5'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:04:15', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '50d79255-39c7-412e-b795-911e5d2f1d3b'	System	17 Sep 2020 04:04:39
User entered 'None (0)'	System	17 Sep 2020 04:04:39

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:04:17', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '50d79255-39c7-412e-b795-911e5d2f1d3b'	System	17 Sep 2020 04:04:39
User entered 'None (0)'	System	17 Sep 2020 04:04:39

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:04:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '50d79255-39c7-412e-b795-911e5d2f1d3b'	System	17 Sep 2020 04:04:39
User entered 'None (0)'	System	17 Sep 2020 04:04:39

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:04:22', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '50d79255-39c7-412e-b795-911e5d2f1d3b'	System	17 Sep 2020 04:04:39
User entered 'None (0)'	System	17 Sep 2020 04:04:39

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:04:24', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '50d79255-39c7-412e-b795-911e5d2f1d3b'	System	17 Sep 2020 04:04:39
User entered 'None (0)'	System	17 Sep 2020 04:04:39

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:04:26', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '50d79255-39c7-412e-b795-911e5d2f1d3b'	System	17 Sep 2020 04:04:39
User entered 'None (0)'	System	17 Sep 2020 04:04:39

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:04:32', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '50d79255-39c7-412e-b795-911e5d2f1d3b'	System	17 Sep 2020 04:04:39
User entered 'No (N)'	System	17 Sep 2020 04:04:39

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-16T21:04:37', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '50d79255-39c7-412e-b795-911e5d2f1d3b'	System	17 Sep 2020 04:04:39
User entered '16 Sep 2020 21:04'	System	17 Sep 2020 04:04:39

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 6'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:47', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0ce034b8-122d-4baf-81f3-db5f3e8583b3'	System	18 Sep 2020 00:42:10
User entered 'None (0)'	System	18 Sep 2020 00:42:10

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:48', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0ce034b8-122d-4baf-81f3-db5f3e8583b3'	System	18 Sep 2020 00:42:10
User entered 'None (0)'	System	18 Sep 2020 00:42:10

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:51', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0ce034b8-122d-4baf-81f3-db5f3e8583b3'	System	18 Sep 2020 00:42:10
User entered 'None (0)'	System	18 Sep 2020 00:42:10

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:53', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0ce034b8-122d-4baf-81f3-db5f3e8583b3'	System	18 Sep 2020 00:42:10
User entered 'None (0)'	System	18 Sep 2020 00:42:10

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:55', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0ce034b8-122d-4baf-81f3-db5f3e8583b3'	System	18 Sep 2020 00:42:10
User entered 'None (0)'	System	18 Sep 2020 00:42:10

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:41:57', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0ce034b8-122d-4baf-81f3-db5f3e8583b3'	System	18 Sep 2020 00:42:10
User entered 'None (0)'	System	18 Sep 2020 00:42:10

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:42:03', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0ce034b8-122d-4baf-81f3-db5f3e8583b3'	System	18 Sep 2020 00:42:10
User entered 'No (N)'	System	18 Sep 2020 00:42:10

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-17T17:42:08', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '0ce034b8-122d-4baf-81f3-db5f3e8583b3'	System	18 Sep 2020 00:42:10
User entered '17 Sep 2020 17:42'	System	18 Sep 2020 00:42:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408697

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408698

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	12 Sep 2020 19:15:59
User entered 'Day 7'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:55:09', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '517f916e-875d-45cc-8fdf-f2c625a5c46d'	System	19 Sep 2020 05:55:18
User entered 'No interference with activity (1)'	System	19 Sep 2020 05:55:18

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:55:02', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '517f916e-875d-45cc-8fdf-f2c625a5c46d'	System	19 Sep 2020 05:55:18
User entered 'Some interference with activity (2)'	System	19 Sep 2020 05:55:18

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:52', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '517f916e-875d-45cc-8fdf-f2c625a5c46d'	System	19 Sep 2020 05:55:18
User entered 'None (0)'	System	19 Sep 2020 05:55:18

Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:49', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '517f916e-875d-45cc-8fdf-f2c625a5c46d'	System	19 Sep 2020 05:55:18
User entered 'None (0)'	System	19 Sep 2020 05:55:18

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:48', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '517f916e-875d-45cc-8fdf-f2c625a5c46d'	System	19 Sep 2020 05:55:18
User entered 'None (0)'	System	19 Sep 2020 05:55:18

US3192291
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:46', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '517f916e-875d-45cc-8fdf-f2c625a5c46d'	System	19 Sep 2020 05:55:18
User entered 'None (0)'	System	19 Sep 2020 05:55:18

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:54:45', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '517f916e-875d-45cc-8fdf-f2c625a5c46d'	System	19 Sep 2020 05:55:18
User entered 'No (N)'	System	19 Sep 2020 05:55:18

US3192291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:16

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-18T22:55:15', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '517f916e-875d-45cc-8fdf-f2c625a5c46d'	System	19 Sep 2020 05:55:18
User entered '18 Sep 2020 22:55'	System	19 Sep 2020 05:55:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 19:15:59

FDA-CBER-2022-1614-0408708

Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 19:15:59

US3192291
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	19 Sep 2020 05:55:18
User entered 'Day 8'	System	19 Sep 2020 05:55:18

US3192291
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 09 Jun 2021 15:40:16

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-19T21:08:11', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '85b1cd39-bb07-4995-8482-4c38450ae06b'	System	20 Sep 2020 04:08:24
User entered 'None (0)'	System	20 Sep 2020 04:08:24

US3192291
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-19T21:08:20', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '85b1cd39-bb07-4995-8482-4c38450ae06b'	System	20 Sep 2020 04:08:24
User entered '19 Sep 2020 21:08'	System	20 Sep 2020 04:08:24

US3192291
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 05:55:18

US3192291

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 05:55:18

US3192291
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	19 Sep 2020 05:55:18
User entered 'Day 8'	System	19 Sep 2020 05:55:18

US3192291
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:40:16

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-19T21:08:27', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'c70f21d2-9b00-4e2e-b323-e9080d6f7ef4'	System	20 Sep 2020 04:08:33
User entered 'No interference with activity (1)'	System	20 Sep 2020 04:08:33

US3192291
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-19T21:08:32', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'c70f21d2-9b00-4e2e-b323-e9080d6f7ef4'	System	20 Sep 2020 04:08:33
User entered '19 Sep 2020 21:08'	System	20 Sep 2020 04:08:33

US3192291

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 05:55:18

US3192291

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 05:55:18

US3192291
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	19 Sep 2020 05:55:18
User entered 'Day 9'	System	19 Sep 2020 05:55:18

US3192291
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 15:40:16

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-21T07:12:20', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b8dde05c-05ce-41f8-9968-702a096c1448'	System	21 Sep 2020 14:12:35
User entered 'None (0)'	System	21 Sep 2020 14:12:35

US3192291
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 15:40:16
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-21T07:12:25', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b8dde05c-05ce-41f8-9968-702a096c1448'	System	21 Sep 2020 14:12:35
User entered '21 Sep 2020 07:12'	System	21 Sep 2020 14:12:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 05:55:18

FDA-CBER-2022-1614-0408723

US3192291

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 05:55:18

US3192291
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	19 Sep 2020 05:55:18
User entered 'Day 8'	System	19 Sep 2020 05:55:18

US3192291

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-19T21:08:37', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '70cde694-2fa7-4412-a80b-5090f6da3a5a'	System	20 Sep 2020 04:08:45
User entered 'No (N)'	System	20 Sep 2020 04:08:45

US3192291
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:40:16
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-19T21:08:41', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '70cde694-2fa7-4412-a80b-5090f6da3a5a'	System	20 Sep 2020 04:08:45
User entered '19 Sep 2020 21:08'	System	20 Sep 2020 04:08:45

US3192291
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 05:55:18

US3192291

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:40:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 05:55:18

US3192291
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
DataPoint Activated.	System	20 Sep 2020 04:08:33
DataPoint Inactivated.	System	20 Sep 2020 04:08:24
Data entry locked.	System	19 Sep 2020 05:55:18
User entered 'Day 9'	System	19 Sep 2020 05:55:18

US3192291

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:40:16

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-21T07:12:31', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd36f69fb-2dc7-4fa2-a379-9ca1c7167a15'	System	21 Sep 2020 14:12:37
User entered 'No (N)'	System	21 Sep 2020 14:12:37
DataPoint Activated.	System	20 Sep 2020 04:08:33
DataPoint Inactivated.	System	20 Sep 2020 04:08:24

US3192291
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:40:16
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-09-21T07:12:35', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'd36f69fb-2dc7-4fa2-a379-9ca1c7167a15'	System	21 Sep 2020 14:12:37
User entered '21 Sep 2020 07:12'	System	21 Sep 2020 14:12:37
DataPoint Activated.	System	20 Sep 2020 04:08:33
DataPoint Inactivated.	System	20 Sep 2020 04:08:24

US3192291

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:40:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
DataPoint Activated.	System	20 Sep 2020 04:08:33
DataPoint Inactivated.	System	20 Sep 2020 04:08:24
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 05:55:18

US3192291
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:40:16
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
DataPoint Activated.	System	20 Sep 2020 04:08:33
DataPoint Inactivated.	System	20 Sep 2020 04:08:24
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 05:55:18

US3192291
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Crystal Mata (b) (4) (b) (4)	20 Sep 2020 15:42:15

US3192291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '20 Sep 2020'	Crystal Mata (b) (4) (b) (4)	20 Sep 2020 15:42:15

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Contact Made (CONTACT MADE)'	Crystal Mata (b) (4) (b) (4)	20 Sep 2020 15:42:15

US3192291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Crystal Mata (b) (4) (b) (4)	20 Sep 2020 15:42:15

US3192291

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Crystal Mata (b) (4) (b) (4)	20 Sep 2020 15:42:21

US3192291
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '1'	System	20 Sep 2020 15:42:21

US3192291
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	25 Sep 2020 21:59:58

US3192291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 17:46:23
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date correct' (Site from System).	maggie Tono (b) (4) (b) (4)	25 Sep 2020 22:01:14
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Sep 2020 21:59:58
User entered '25 Sep 2020'	maggie Tono (b) (4) (b) (4)	25 Sep 2020 21:59:58

US3192291
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Contact Made (CONTACT MADE)'	maggie Tono (b) (4) (b) (4)	25 Sep 2020 21:59:58

US3192291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	maggie Tono (b) (4) (b) (4)	25 Sep 2020 21:59:58

US3192291

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	maggie Tono (b) (4) (b) (4)	25 Sep 2020 22:01:20

US3192291
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '1'	System	25 Sep 2020 22:01:20

US3192291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
Query 'Per GCL Lab Reconciliation Requery: Antibody-mediated Immunogenicity: Please review if Visit 3 Day 57visit Sample dated 10OCT2020 has been collected then update the details under Visit 3 Day57 visit Immunogenicity assessment form as the sample is reported under in PPD Central lab, Else clarify, thank you' canceled (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:32:53
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 29OCT2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:31:58
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 29OCT2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'EDC has been updated' (Site from DM).	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:19:20
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 29OCT2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:34:33
User opened query 'Per GCL Lab Reconciliation Requery: Antibody-mediated Immunogenicity: Please review if Visit 3 Day 57visit Sample dated 10OCT2020 has been collected then update the details under Visit 3 Day57 visit Immunogenicity assessment form as the sample is reported under in PPD Central lab, Else clarify, thank you' (Site from DM).		04 Nov 2020 07:44:22

US3192291
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:44:22
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'demo sheet has been submitted ' (Site from DM).	maggie Tono (b) (4) (b) (4)	21 Oct 2020 16:21:04
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 11:40:01
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	03 Oct 2020 16:10:26

US3192291
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User entered '03 Oct 2020'	Zoe Sesma (b) (4) (b) (4)	03 Oct 2020 16:10:26

US3192291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4) (b) (4)	03 Oct 2020 16:10:26

US3192291
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User entered empty.	Zoe Sesma (b) (4) (b) (4)	03 Oct 2020 16:10:26

US3192291
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	03 Oct 2020 16:10:30

US3192291
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '1'	System	03 Oct 2020 16:10:30

US3192291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:57:59

US3192291
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 29OCT2020 under Illness Visit Day 1 in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:32:18
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 29OCT2020 under Illness Visit Day 1 in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' answered with 'Updated' (Site from DM).	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:18:32
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 29OCT2020 under Illness Visit Day 1 in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 15:34:18
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	11 Dec 2020 22:59:06
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	11 Dec 2020 22:59:06
User entered '10 Oct 2020' reason for change: Data Entry Error	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:59:06
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	11 Dec 2020 22:57:59
User entered '10 Dec 2020'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:57:59

US3192291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User entered 'Clinic (Clinic)'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:57:59

US3192291
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'VISIT3'	System	11 Dec 2020 22:57:59

US3192291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:58:43

US3192291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Dec 2020 22:59:06
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	11 Dec 2020 22:59:06
User entered '10 Oct 2020' reason for change: Data Entry Error	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:58:56
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Dec 2020 22:58:43
User entered '11 Dec 2020'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:58:43

US3192291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '11:46'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:58:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '10 Oct 2020 11:46'	System	11 Dec 2020 22:58:56
User entered '11 Dec 2020 11:46'	System	11 Dec 2020 22:58:43

US3192291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '98.6' F	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:58:43

US3192291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Oral (Oral)'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:58:43

US3192291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered empty.	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:58:43

US3192291
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '67'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:58:43

US3192291
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'bpm'	System	11 Dec 2020 22:58:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '14'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:58:43

US3192291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'breaths/min'	System	11 Dec 2020 22:58:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '118'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:58:43

FDA-CBER-2022-1614-0408769

US3192291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'mmHg'	System	11 Dec 2020 22:58:43

US3192291
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '78'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:58:43

US3192291
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered 'mmHg'	System	11 Dec 2020 22:58:43

US3192291
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26

US3192291
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26

US3192291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:59:18

US3192291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Dec 2020 22:59:25
User entered '10 Oct 2020' reason for change: Data Entry Error	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:59:25
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Dec 2020 22:59:18
User entered '11 Dec 2020'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 22:59:18

Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:16
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 23:00:02

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '10 Oct 2020'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 23:00:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered '12:08'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 23:00:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '10 Oct 2020 12:08'	System	11 Dec 2020 23:00:02

FDA-CBER-2022-1614-0408780

US3192291
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:36:56
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	11 Dec 2020 23:00:06

US3192291
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '1'	System	11 Dec 2020 23:00:06

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 64'	System	16 Aug 2020 17:22:07

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-10-16T08:20:50', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '551d80ac-d639-4de9-bfbb-c8452f8e6976'	System	16 Oct 2020 15:21:05
User entered 'No (N)'	System	16 Oct 2020 15:21:05

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-10-16T08:20:54', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '551d80ac-d639-4de9-bfbb-c8452f8e6976'	System	16 Oct 2020 15:21:05
User entered 'No (N)'	System	16 Oct 2020 15:21:05

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-10-16T08:20:59', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '551d80ac-d639-4de9-bfbb-c8452f8e6976'	System	16 Oct 2020 15:21:05
User entered '16 Oct 2020 08:20:59'	System	16 Oct 2020 15:21:05

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered '16 Oct 2020 00:01'	System	16 Aug 2020 17:22:07

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered '20 Oct 2020 23:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 71'	System	16 Aug 2020 17:22:07

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-10-23T03:03:13', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f9c7d5f4-da9a-4a0d-810f-4e648406690b'	System	23 Oct 2020 10:03:31
User entered 'No (N)'	System	23 Oct 2020 10:03:31

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-10-23T03:03:22', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f9c7d5f4-da9a-4a0d-810f-4e648406690b'	System	23 Oct 2020 10:03:31
User entered 'No (N)'	System	23 Oct 2020 10:03:31

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-10-23T03:03:28', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'f9c7d5f4-da9a-4a0d-810f-4e648406690b'	System	23 Oct 2020 10:03:31
User entered '23 Oct 2020 03:03:28'	System	23 Oct 2020 10:03:31

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered '23 Oct 2020 00:01'	System	16 Aug 2020 17:22:07

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered '27 Oct 2020 23:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 78'	System	16 Aug 2020 17:22:07

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Please 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)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Please 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)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Please 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)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32
Data entry locked.	System	16 Aug 2020 17:22:07
User entered '30 Oct 2020 00:01'	System	16 Aug 2020 17:22:07

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:46:32
Data entry locked.	System	16 Aug 2020 17:22:07
User entered '03 Nov 2020 23:59'	System	16 Aug 2020 17:22:07

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered 'Day 92'	System	16 Aug 2020 17:22:07

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-13T14:34:44', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '9193fafe-3c72-48d7-bda8-6fe4815a108c'	System	13 Nov 2020 21:35:41
User entered 'Yes (Y)'	System	13 Nov 2020 21:35:41

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-13T14:34:51', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '9193fafe-3c72-48d7-bda8-6fe4815a108c'	System	13 Nov 2020 21:35:41
User entered 'No (N)'	System	13 Nov 2020 21:35:41

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-13T14:35:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '9193fafe-3c72-48d7-bda8-6fe4815a108c'	System	13 Nov 2020 21:35:41
User entered 'No (N)'	System	13 Nov 2020 21:35:41

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-13T14:35:07', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '9193fafe-3c72-48d7-bda8-6fe4815a108c'	System	13 Nov 2020 21:35:41
User entered 'Yes (Y)'	System	13 Nov 2020 21:35:41

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Please 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 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-13T14:35:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '9193fafe-3c72-48d7-bda8-6fe4815a108c'	System	13 Nov 2020 21:35:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 21:35:41

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-13T14:35:29', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '9193fafe-3c72-48d7-bda8-6fe4815a108c'	System	13 Nov 2020 21:35:41
User entered '13 Nov 2020 14:35:29'	System	13 Nov 2020 21:35:41

US3192291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered '13 Nov 2020 00:01'	System	16 Aug 2020 17:22:07

US3192291
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:46:14
Data entry locked.	System	16 Aug 2020 17:22:07
User entered '17 Nov 2020 23:59'	System	16 Aug 2020 17:22:07

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:15:49
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'patient confirmed the day she had a appt with her healthcare provider' (Site from DM).	maggie Tono (b) (4) (b) (4)	20 Jan 2021 23:44:57
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 03:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-20T19:09:53', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'aa14c7bd-5157-4409-afff-36047130a149'	System	21 Nov 2020 02:10:42
User entered 'Yes (Y)'	System	21 Nov 2020 02:10:42

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-20T19:09:58', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'aa14c7bd-5157-4409-afff-36047130a149'	System	21 Nov 2020 02:10:42
User entered 'No (N)'	System	21 Nov 2020 02:10:42

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-20T19:10:05', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'aa14c7bd-5157-4409-afff-36047130a149'	System	21 Nov 2020 02:10:42
User entered 'No (N)'	System	21 Nov 2020 02:10:42

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-20T19:10:13', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'aa14c7bd-5157-4409-afff-36047130a149'	System	21 Nov 2020 02:10:42
User entered 'Yes (Y)'	System	21 Nov 2020 02:10:42

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Please 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-20T19:10:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'aa14c7bd-5157-4409-afff-36047130a149'	System	21 Nov 2020 02:10:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Nov 2020 02:10:42

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-20T19:10:24', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'aa14c7bd-5157-4409-afff-36047130a149'	System	21 Nov 2020 02:10:42
User entered '20 Nov 2020 19:10:24'	System	21 Nov 2020 02:10:42

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:15:37
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'patient does not remember about having another appt with her healthcare provider ' (Site from DM).	maggie Tono (b) (4) (b) (4)	20 Jan 2021 23:44:39
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 03:15:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-24T12:49:29', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '72ab1810-ff14-472b-8c77-c3649be675a3'	System	24 Nov 2020 19:50:31
User entered 'Yes (Y)'	System	24 Nov 2020 19:50:31

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-24T12:49:38', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '72ab1810-ff14-472b-8c77-c3649be675a3'	System	24 Nov 2020 19:50:31
User entered 'No (N)'	System	24 Nov 2020 19:50:31

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-24T12:49:49', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '72ab1810-ff14-472b-8c77-c3649be675a3'	System	24 Nov 2020 19:50:31
User entered 'No (N)'	System	24 Nov 2020 19:50:31

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-24T12:49:59', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '72ab1810-ff14-472b-8c77-c3649be675a3'	System	24 Nov 2020 19:50:31
User entered 'Yes (Y)'	System	24 Nov 2020 19:50:31

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Please 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-24T12:50:11', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '72ab1810-ff14-472b-8c77-c3649be675a3'	System	24 Nov 2020 19:50:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 19:50:31

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-11-24T12:50:21', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '72ab1810-ff14-472b-8c77-c3649be675a3'	System	24 Nov 2020 19:50:31
User entered '24 Nov 2020 12:50:21'	System	24 Nov 2020 19:50:31

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0408849

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-01T20:38:48', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '88923daf-a3f1-4777-bb4b-e1a7b15eb0bd'	System	02 Dec 2020 03:39:28
User entered 'Yes (Y)'	System	02 Dec 2020 03:39:28

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-01T20:38:54', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '88923daf-a3f1-4777-bb4b-e1a7b15eb0bd'	System	02 Dec 2020 03:39:28
User entered 'No (N)'	System	02 Dec 2020 03:39:28

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-01T20:39:01', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '88923daf-a3f1-4777-bb4b-e1a7b15eb0bd'	System	02 Dec 2020 03:39:28
User entered 'No (N)'	System	02 Dec 2020 03:39:28

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-01T20:39:08', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '88923daf-a3f1-4777-bb4b-e1a7b15eb0bd'	System	02 Dec 2020 03:39:28
User entered 'Yes (Y)'	System	02 Dec 2020 03:39:28

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Please 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-01T20:39:13', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '88923daf-a3f1-4777-bb4b-e1a7b15eb0bd'	System	02 Dec 2020 03:39:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Dec 2020 03:39:28

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-01T20:39:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '88923daf-a3f1-4777-bb4b-e1a7b15eb0bd'	System	02 Dec 2020 03:39:28
User entered '01 Dec 2020 20:39:19'	System	02 Dec 2020 03:39:28

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-10T13:04:04', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '7ed8b6c5-ae40-4b13-acc2-455c68b1260a'	System	10 Dec 2020 20:04:16
User entered 'No (N)'	System	10 Dec 2020 20:04:16

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-10T13:04:07', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '7ed8b6c5-ae40-4b13-acc2-455c68b1260a'	System	10 Dec 2020 20:04:16
User entered 'No (N)'	System	10 Dec 2020 20:04:16

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-10T13:04:12', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '7ed8b6c5-ae40-4b13-acc2-455c68b1260a'	System	10 Dec 2020 20:04:16
User entered '10 Dec 2020 13:04:12'	System	10 Dec 2020 20:04:16

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 08:46:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 08:46:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-17T15:12:29', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '6b38049a-add6-4180-9583-20b9a16cc869'	System	17 Dec 2020 22:12:39
User entered 'No (N)'	System	17 Dec 2020 22:12:39

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-17T15:12:32', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '6b38049a-add6-4180-9583-20b9a16cc869'	System	17 Dec 2020 22:12:39
User entered 'No (N)'	System	17 Dec 2020 22:12:39

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-17T15:12:36', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '6b38049a-add6-4180-9583-20b9a16cc869'	System	17 Dec 2020 22:12:39
User entered '17 Dec 2020 15:12:36'	System	17 Dec 2020 22:12:39

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-22T12:05:43', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'df5a2da7-0972-4f4b-9325-6304c0510cd9'	System	22 Dec 2020 19:05:56
User entered 'No (N)'	System	22 Dec 2020 19:05:56

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-22T12:05:46', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'df5a2da7-0972-4f4b-9325-6304c0510cd9'	System	22 Dec 2020 19:05:56
User entered 'No (N)'	System	22 Dec 2020 19:05:56

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-22T12:05:53', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'df5a2da7-0972-4f4b-9325-6304c0510cd9'	System	22 Dec 2020 19:05:56
User entered '22 Dec 2020 12:05:53'	System	22 Dec 2020 19:05:56

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-29T01:52:21', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1e15308a-927e-4008-8367-669f16dc06bf'	System	29 Dec 2020 08:52:37
User entered 'No (N)'	System	29 Dec 2020 08:52:37

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-29T01:52:27', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1e15308a-927e-4008-8367-669f16dc06bf'	System	29 Dec 2020 08:52:37
User entered 'No (N)'	System	29 Dec 2020 08:52:37

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2020-12-29T01:52:33', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '1e15308a-927e-4008-8367-669f16dc06bf'	System	29 Dec 2020 08:52:37
User entered '29 Dec 2020 01:52:33'	System	29 Dec 2020 08:52:37

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-05T10:03:30', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2c5bac28-d968-4298-85cd-4b96105a62f2'	System	05 Jan 2021 17:03:42
User entered 'No (N)'	System	05 Jan 2021 17:03:42

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-05T10:03:33', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2c5bac28-d968-4298-85cd-4b96105a62f2'	System	05 Jan 2021 17:03:42
User entered 'No (N)'	System	05 Jan 2021 17:03:42

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-05T10:03:38', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2c5bac28-d968-4298-85cd-4b96105a62f2'	System	05 Jan 2021 17:03:42
User entered '05 Jan 2021 10:03:38'	System	05 Jan 2021 17:03:42

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-12T10:30:02', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '27eed46c-064b-4e9b-a6b9-7d93872b835b'	System	12 Jan 2021 17:30:33
User entered 'No (N)'	System	12 Jan 2021 17:30:33

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-12T10:29:48', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '27eed46c-064b-4e9b-a6b9-7d93872b835b'	System	12 Jan 2021 17:30:33
User entered 'No (N)'	System	12 Jan 2021 17:30:33

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-12T10:30:30', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '27eed46c-064b-4e9b-a6b9-7d93872b835b'	System	12 Jan 2021 17:30:33
User entered '12 Jan 2021 10:30:30'	System	12 Jan 2021 17:30:33

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0408894

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-21T11:49:28', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e5982f42-a570-4855-a585-f0b49fd0730c'	System	21 Jan 2021 18:49:42
User entered 'No (N)'	System	21 Jan 2021 18:49:42

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-21T11:49:31', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e5982f42-a570-4855-a585-f0b49fd0730c'	System	21 Jan 2021 18:49:42
User entered 'No (N)'	System	21 Jan 2021 18:49:42

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-21T11:49:37', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e5982f42-a570-4855-a585-f0b49fd0730c'	System	21 Jan 2021 18:49:42
User entered '21 Jan 2021 11:49:37'	System	21 Jan 2021 18:49:42

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-27T12:55:41', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b96a3f7d-b1c8-40bb-a771-f6733ee63253'	System	27 Jan 2021 20:19:49
User entered 'No (N)'	System	27 Jan 2021 20:19:49

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-27T13:19:19', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b96a3f7d-b1c8-40bb-a771-f6733ee63253'	System	27 Jan 2021 20:19:49
User entered 'No (N)'	System	27 Jan 2021 20:19:49

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-01-27T13:19:28', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b96a3f7d-b1c8-40bb-a771-f6733ee63253'	System	27 Jan 2021 20:19:49
User entered '27 Jan 2021 13:19:28'	System	27 Jan 2021 20:19:49

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-02T09:24:54', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '82403643-69bc-43c7-81e2-3d7495d32fc6'	System	02 Feb 2021 16:25:07
User entered 'No (N)'	System	02 Feb 2021 16:25:07

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-02T09:24:57', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '82403643-69bc-43c7-81e2-3d7495d32fc6'	System	02 Feb 2021 16:25:07
User entered 'No (N)'	System	02 Feb 2021 16:25:07

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-02T09:25:02', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '82403643-69bc-43c7-81e2-3d7495d32fc6'	System	02 Feb 2021 16:25:07
User entered '02 Feb 2021 09:25:02'	System	02 Feb 2021 16:25:07

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-09T14:24:05', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '5b56d021-6a86-4411-afd4-951a41bc8760'	System	09 Feb 2021 21:24:18
User entered 'No (N)'	System	09 Feb 2021 21:24:18

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-09T14:24:09', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '5b56d021-6a86-4411-afd4-951a41bc8760'	System	09 Feb 2021 21:24:18
User entered 'No (N)'	System	09 Feb 2021 21:24:18

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-09T14:24:12', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '5b56d021-6a86-4411-afd4-951a41bc8760'	System	09 Feb 2021 21:24:18
User entered '09 Feb 2021 14:24:12'	System	09 Feb 2021 21:24:18

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-17T10:44:53', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '64245b3d-abb0-4785-8576-68bc44c177c9'	System	17 Feb 2021 17:45:03
User entered 'No (N)'	System	17 Feb 2021 17:45:03

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-17T10:44:56', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '64245b3d-abb0-4785-8576-68bc44c177c9'	System	17 Feb 2021 17:45:03
User entered 'No (N)'	System	17 Feb 2021 17:45:03

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-17T10:45:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '64245b3d-abb0-4785-8576-68bc44c177c9'	System	17 Feb 2021 17:45:03
User entered '17 Feb 2021 10:45:00'	System	17 Feb 2021 17:45:03

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-23T10:35:55', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '6085b336-31de-4de1-b378-25296eaca3f8'	System	23 Feb 2021 17:36:07
User entered 'No (N)'	System	23 Feb 2021 17:36:07

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-23T10:35:58', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '6085b336-31de-4de1-b378-25296eaca3f8'	System	23 Feb 2021 17:36:07
User entered 'No (N)'	System	23 Feb 2021 17:36:07

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-02-23T10:36:02', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '6085b336-31de-4de1-b378-25296eaca3f8'	System	23 Feb 2021 17:36:07
User entered '23 Feb 2021 10:36:02'	System	23 Feb 2021 17:36:07

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-02T08:48:00-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2f31c1ec-8784-476b-a5c2-75ab2e0b2fe0'	System	02 Mar 2021 15:48:14
User entered 'No (N)'	System	02 Mar 2021 15:48:14

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-02T08:48:04-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2f31c1ec-8784-476b-a5c2-75ab2e0b2fe0'	System	02 Mar 2021 15:48:14
User entered 'No (N)'	System	02 Mar 2021 15:48:14

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-02T08:48:08-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '2f31c1ec-8784-476b-a5c2-75ab2e0b2fe0'	System	02 Mar 2021 15:48:14
User entered '02 Mar 2021 15:48:08'	System	02 Mar 2021 15:48:14

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0408936

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-11T14:22:07-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '359e560e-5e83-4aa1-8269-e62ea48761a0'	System	11 Mar 2021 21:22:19
User entered 'No (N)'	System	11 Mar 2021 21:22:19

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-11T14:22:10-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '359e560e-5e83-4aa1-8269-e62ea48761a0'	System	11 Mar 2021 21:22:19
User entered 'No (N)'	System	11 Mar 2021 21:22:19

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-11T14:22:15-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '359e560e-5e83-4aa1-8269-e62ea48761a0'	System	11 Mar 2021 21:22:19
User entered '11 Mar 2021 14:22:15'	System	11 Mar 2021 21:22:19

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-16T08:12:40-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b5accca2-f311-4be8-abdf-21688848aff0'	System	16 Mar 2021 15:12:49
User entered 'No (N)'	System	16 Mar 2021 15:12:49

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-16T08:12:44-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b5accca2-f311-4be8-abdf-21688848aff0'	System	16 Mar 2021 15:12:49
User entered 'No (N)'	System	16 Mar 2021 15:12:49

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-16T08:12:47-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b5accca2-f311-4be8-abdf-21688848aff0'	System	16 Mar 2021 15:12:49
User entered '16 Mar 2021 08:12:47'	System	16 Mar 2021 15:12:49

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-23T09:19:13-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '3d23ed0a-8037-4d2a-8c42-6331cbfc626a'	System	23 Mar 2021 16:19:27
User entered 'No (N)'	System	23 Mar 2021 16:19:27

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-23T09:19:17-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '3d23ed0a-8037-4d2a-8c42-6331cbfc626a'	System	23 Mar 2021 16:19:27
User entered 'No (N)'	System	23 Mar 2021 16:19:27

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-23T09:19:22-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '3d23ed0a-8037-4d2a-8c42-6331cbfc626a'	System	23 Mar 2021 16:19:27
User entered '23 Mar 2021 09:19:22'	System	23 Mar 2021 16:19:27

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-30T10:21:30-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b668f9eb-1056-470c-8498-91fe002a32e7'	System	30 Mar 2021 17:21:41
User entered 'No (N)'	System	30 Mar 2021 17:21:41

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-30T10:21:33-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b668f9eb-1056-470c-8498-91fe002a32e7'	System	30 Mar 2021 17:21:41
User entered 'No (N)'	System	30 Mar 2021 17:21:41

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-30T10:21:36-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b668f9eb-1056-470c-8498-91fe002a32e7'	System	30 Mar 2021 17:21:41
User entered '30 Mar 2021 10:21:36'	System	30 Mar 2021 17:21:41

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-06T13:54:03-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a70c8e61-c5ce-4ee2-9c28-edd3e42c2c80'	System	06 Apr 2021 20:54:14
User entered 'No (N)'	System	06 Apr 2021 20:54:14

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-06T13:54:07-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a70c8e61-c5ce-4ee2-9c28-edd3e42c2c80'	System	06 Apr 2021 20:54:14
User entered 'No (N)'	System	06 Apr 2021 20:54:14

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-06T13:54:10-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'a70c8e61-c5ce-4ee2-9c28-edd3e42c2c80'	System	06 Apr 2021 20:54:14
User entered '06 Apr 2021 13:54:10'	System	06 Apr 2021 20:54:14

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-16T18:16:06-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'ac90cc58-f9ac-4e30-a1b9-9252bc7c3abd'	System	17 Apr 2021 01:16:22
User entered 'No (N)'	System	17 Apr 2021 01:16:22

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-16T18:16:09-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'ac90cc58-f9ac-4e30-a1b9-9252bc7c3abd'	System	17 Apr 2021 01:16:22
User entered 'No (N)'	System	17 Apr 2021 01:16:22

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-16T18:16:17-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'ac90cc58-f9ac-4e30-a1b9-9252bc7c3abd'	System	17 Apr 2021 01:16:22
User entered '16 Apr 2021 18:16:17'	System	17 Apr 2021 01:16:22

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 08:46:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0408973

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-20T07:59:30-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b3747cf8-60a4-4c19-af47-59e24403132b'	System	20 Apr 2021 14:59:39
User entered 'No (N)'	System	20 Apr 2021 14:59:39

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-20T07:59:33-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b3747cf8-60a4-4c19-af47-59e24403132b'	System	20 Apr 2021 14:59:39
User entered 'No (N)'	System	20 Apr 2021 14:59:39

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-20T07:59:37-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'b3747cf8-60a4-4c19-af47-59e24403132b'	System	20 Apr 2021 14:59:39
User entered '20 Apr 2021 07:59:37'	System	20 Apr 2021 14:59:39

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 08:46:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-27T10:54:12-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e4e3e9ad-a69a-4311-a471-550f102edc07'	System	29 Apr 2021 05:28:29
User entered 'No (N)'	System	29 Apr 2021 05:28:29

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Have you been exposed to someone with 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 (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-27T10:54:16-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e4e3e9ad-a69a-4311-a471-550f102edc07'	System	29 Apr 2021 05:28:29
User entered 'No (N)'	System	29 Apr 2021 05:28:29

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-04-27T10:54:20-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: 'e4e3e9ad-a69a-4311-a471-550f102edc07'	System	29 Apr 2021 05:28:29
User entered '27 Apr 2021 10:54:20'	System	29 Apr 2021 05:28:29

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 08:46:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409030

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409035

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 08:46:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409042

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 08:46:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409045

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 08:46:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:46:32

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409070

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409077

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 08:46:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409104

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 08:46:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409108

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 08:46:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 08:46:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409156

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409164

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 08:46:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 08:46:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409177

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409188

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 08:46:32

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409198

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 08:46:32

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409209

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:46:32

FDA-CBER-2022-1614-0409210

US3192291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:16

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '11 Oct 2022 00:01'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '15 Oct 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:46:32

US3192291
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:40:16
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '18 Oct 2022 00:01'	System	19 Nov 2020 08:46:32

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:32
Amendment Manager: User entered '22 Oct 2022 23:59'	System	19 Nov 2020 08:46:32

US3192291

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:40:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-19T18:00:48-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '6def6294-0926-47c7-8c6f-8486fac001f9'	System	20 Mar 2021 01:02:43
User entered 'No (N)'	System	20 Mar 2021 01:02:43

US3192291

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:40:16

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:28:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (917D729B-6DEF-495B-BA74-4960A9F62B61)', Time: '2021-03-19T18:00:54-07:00', User OID: 'PatientReportedOutcome (US3192291)', ODM File OID: '6def6294-0926-47c7-8c6f-8486fac001f9'	System	20 Mar 2021 01:02:43
User entered '19 Mar 2021 18:00:54'	System	20 Mar 2021 01:02:43

US3192291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 21:32:44

US3192291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
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)	14 Jan 2021 16:35:18
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 'patient was in ICU ' (Site from System).	(b) (4), (b) (6)	11 Jan 2021 21:33:18
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	11 Jan 2021 21:32:44
User entered '12 Nov 2020'	(b) (4), (b) (6)	11 Jan 2021 21:32:44

Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Jan 2021 21:32:44

FDA-CBER-2022-1614-0409220

US3192291
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 21:32:44

US3192291
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:14:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 21:33:25

US3192291
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 12:05:26
User entered '1'	System	11 Jan 2021 21:33:25

US3192291
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 21:33:49

US3192291

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered '11 Dec 2020'	(b) (4), (b) (6)	11 Jan 2021 21:33:49

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Jan 2021 21:33:49

US3192291
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:33:49

US3192291
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 21:33:53

US3192291
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User entered '1'	System	11 Jan 2021 21:33:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:49:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 21:35:55

FDA-CBER-2022-1614-0409230

Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:49:41
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29OCT2020 under Illness Visit Day 1 in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:40:59
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29OCT2020 under Illness Visit Day 1 in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' answered with 'it is under the illness 29 oct 2020' (Site from DM).	maggie Tono (b) (4) (b) (4)	13 Mar 2021 21:44:01
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29OCT2020 under Illness Visit Day 1 in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 10:28:21
User entered '11 Jan 2021'		11 Jan 2021 21:35:55

Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:49:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Jan 2021 21:35:55

US3192291
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:49:41
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 21:35:55

US3192291

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:36:00

US3192291
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User entered '1'	System	11 Jan 2021 21:36:00

US3192291
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:49:41
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 18:42:38

US3192291

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 18:42:38

US3192291
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 18:42:38

US3192291
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:42:38

US3192291
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:49:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:25:02

US3192291
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:53:21
User entered '1'	System	19 Mar 2021 20:25:02

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:25:16

US3192291
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:41
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:25:16

US3192291
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:41
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Mar 2021 20:25:16

US3192291
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User entered 'VISIT4'	System	19 Mar 2021 20:25:16

US3192291
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:54:26

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered '19 Mar 2021'	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:54:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered '10:50'	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:54:26

FDA-CBER-2022-1614-0409248

US3192291
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User entered '19 Mar 2021 10:50'	System	30 Mar 2021 17:54:26

US3192291
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered '98.7' F	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:54:26

US3192291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered 'Oral (Oral)'	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:54:26

US3192291
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered empty.	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:54:26

Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered '69'	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:54:26

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User entered 'bpm'	System	30 Mar 2021 17:54:26

FDA-CBER-2022-1614-0409254

US3192291
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered '12'	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:54:26

US3192291
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User entered 'breaths/min'	System	30 Mar 2021 17:54:26

Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered '135'	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:54:26

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User entered 'mmHg'	System	30 Mar 2021 17:54:26

US3192291
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered '82'	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:54:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User entered 'mmHg'	System	30 Mar 2021 17:54:26

FDA-CBER-2022-1614-0409260

US3192291
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51

US3192291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:25:25

US3192291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:41
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:25:25

US3192291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User closed query '??????????Per CDM: Visit 4 Day and OL-D57 are both dated 19MAR2021 however, the data on the Immunogenicity Assessment forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 22:59:23
Query '??????????Per CDM: Visit 4 Day 209 and OL-D57 are both dated 19MAR2021 however, the data on the Immunogenicity Assessment forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:54:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:53:59
User opened query '??????????Per CDM: Visit 4 Day and OL-D57 are both dated 19MAR2021 however, the data on the Immunogenicity Assessment forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:17:59
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 20:25:29

US3192291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered '19 Mar 2021' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:53:59
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 20:25:29

US3192291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered '10:50' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	30 Mar 2021 17:53:59
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 20:25:29

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User entered '19 Mar 2021 10:50'	System	30 Mar 2021 17:53:59
User entered empty.	System	19 Mar 2021 20:25:29

US3192291
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:25:34

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:51:51
User entered '1'	System	19 Mar 2021 20:25:34

US3192291

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User		Time (GMT)
User signature succeeded.	John McGettigan	(b) (4)	15 Apr 2021 15:33:38
	(b) (4)		
User entered 'Yes (Y)'	Damaris Atondo	(b) (4)	14 Apr 2021 16:29:49
	(b) (4)		

US3192291
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	15 Apr 2021 15:33:38
User entered '13 Apr 2021'	Damaris Atondo (b) (4) (b) (4)	14 Apr 2021 16:29:49

US3192291
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	15 Apr 2021 15:33:38
User entered 'Contact Made (CONTACT MADE)'	Damaris Atondo (b) (4) (b) (4)	14 Apr 2021 16:29:49

US3192291
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	15 Apr 2021 15:33:38
User entered empty.	Damaris Atondo (b) (4) (b) (4)	14 Apr 2021 16:29:49

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	15 Apr 2021 15:33:38
User entered 'Yes (Y)'	Damaris Atondo (b) (4) (b) (4)	14 Apr 2021 16:29:53

US3192291
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 16:29:53

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:40:16
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '28 Oct 2020'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:14

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:40:16

Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '15:00'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:14

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:40:16
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User entered '28 Oct 2020 15:00'	System	25 Feb 2021 22:22:14

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:40:16

Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Safety Call (Safety Call)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:14

Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:40:16

Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:14

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Day 1 (Day 1)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

FDA-CBER-2022-1614-0409282

Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:40:16
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '27 Oct 2020'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:40:16
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '0'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:16

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered missing code ND - Not Done.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User entered '%'	System	25 Feb 2021 22:26:02

FDA-CBER-2022-1614-0409286

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:40:16
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '97.0' F	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:40:16
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Mild (Mild)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:16

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:40:16
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

FDA-CBER-2022-1614-0409290

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

FDA-CBER-2022-1614-0409291

Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:40:16

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:16

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:40:16
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:40:16

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

FDA-CBER-2022-1614-0409296

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

FDA-CBER-2022-1614-0409297

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:16

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

FDA-CBER-2022-1614-0409300

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

FDA-CBER-2022-1614-0409301

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:16

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:02

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:16

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Day 2 (Day 2)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:16

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '28 Oct 2020'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:16

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '0'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:40:16
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered missing code ND - Not Done.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:40:16
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User entered '%'	System	25 Feb 2021 22:26:47

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:40:16
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered missing code ND - Not Done.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:40:16
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

FDA-CBER-2022-1614-0409311

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

FDA-CBER-2022-1614-0409312

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:40:16
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:16

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:16

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:40:16
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:16

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

FDA-CBER-2022-1614-0409319

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:16

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

FDA-CBER-2022-1614-0409321

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:40:16
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:40:16
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Mild (Mild)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Mild (Mild)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

FDA-CBER-2022-1614-0409324

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:40:16
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:26:47

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Day 3 (Day 3)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

FDA-CBER-2022-1614-0409326

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '29 Oct 2020'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:16

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '0'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:40:16
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '95'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:40:16
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User entered '%'	System	25 Feb 2021 22:28:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '101.1' F	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

FDA-CBER-2022-1614-0409331

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:16

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Severe (Severe)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:16

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Mild (Mild)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:40:16
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:40:16
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Severe (Severe)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:16

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Severe (Severe)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:40:16
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Severe (Severe)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:40:16
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Moderate (Moderate)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Moderate (Moderate)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

FDA-CBER-2022-1614-0409340

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:16

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Moderate (Moderate)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

FDA-CBER-2022-1614-0409342

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:16

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:40:16

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Mild (Mild)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:40:16
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Moderate (Moderate)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:16

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Moderate (Moderate)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:40:16
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'None (None)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:28:23

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:40:16
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '29 Oct 2020'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:35

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:16

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:35

US3192291

Folder: Covid-19 Assessment 28 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:16

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:35

Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered '29 Oct 2020'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:35

FDA-CBER-2022-1614-0409351

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:40:16

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:35

Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered empty.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:35

FDA-CBER-2022-1614-0409353

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:35

FDA-CBER-2022-1614-0409354

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:40:16

Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered empty.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:35

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:40:16

CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered empty.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:22:35

US3192291
Folder: Covid-19 Assessment 28 Oct 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:40:16
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:12
User entered '0'	System	25 Feb 2021 22:22:35

US3192291
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 15:40:16
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:40:16

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'NA (COVID-19 Negative) (NA)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:40:16

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:40:16

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:40:16

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'NA (COVID-19 Negative) (NA)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:40:16

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:40:16

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:40:16

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'NA (COVID-19 Negative) (NA)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:40:16

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:40:16

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:40:16

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'NA (COVID-19 Negative) (NA)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:40:16

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:40:16

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:40:16

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'NA (COVID-19 Negative) (NA)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:40:16

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 15:40:16

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:40:16

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'NA (COVID-19 Negative) (NA)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:40:16

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:40:16

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:40:16

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'NA (COVID-19 Negative) (NA)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:40:16

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:16:51

US3192291

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:14:11

US3192291
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '29 Oct 2020'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:14:11

US3192291

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

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 21:35:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Clinic (Clinic)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:14:11

US3192291
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:15
User entered 'SICKD1'	System	25 Feb 2021 22:14:11

US3192291
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36

US3192291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '29 Oct 2020'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36

US3192291
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '17:25'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36

US3192291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User entered '29 Oct 2020 17:25'	System	25 Feb 2021 22:15:36

US3192291
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '61' in	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36
DataPoint set to visible.	System	25 Feb 2021 22:14:11

FDA-CBER-2022-1614-0409387

US3192291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '158.2' lb	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36
DataPoint set to visible.	System	25 Feb 2021 22:14:11

US3192291
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '99.1' F	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36

US3192291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Oral (Oral)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36

US3192291
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36

US3192291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '75'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36

FDA-CBER-2022-1614-0409392

US3192291
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User entered 'bpm'	System	25 Feb 2021 22:15:36

US3192291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '12'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36

US3192291
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User entered 'breaths/min'	System	25 Feb 2021 22:15:36

US3192291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '115'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36

US3192291
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User entered 'mmHg'	System	25 Feb 2021 22:15:36

US3192291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '78'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:15:36

US3192291
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08
User entered 'mmHg'	System	25 Feb 2021 22:15:36

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08

US3192291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:08

Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:02
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:14:35

FDA-CBER-2022-1614-0409402

US3192291

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:35:02
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '29 Oct 2020'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:14:35

US3192291

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:40:16

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:34:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:14:23

US3192291

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:40:16

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:34:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '29 Oct 2020'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 22:14:23

US3192291

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

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:43:37

US3192291
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '22 Jan 2021'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:43:37

US3192291

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

Form: Visit Date

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Clinic (Clinic)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:43:37

US3192291
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 23:43:37

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '22 Jan 2021'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:43:48

US3192291

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:16

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 17:53:54
User entered '0'	Amanda Hermosillo (b) (4)	09 Apr 2021 18:38:15
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:49:48

US3192291

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:16

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:43:48

US3192291

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:16

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
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).		16 Apr 2021 03:58:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	12 Apr 2021 17:53:54
Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM).	Amanda Hermosillo (b) (4)	09 Apr 2021 18:38:48
User entered 'Amendment 6 or later (Amendment 6 or later)'	Amanda Hermosillo (b) (4)	09 Apr 2021 18:38:15
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)	09 Apr 2021 17:44:30
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:49:48

US3192291

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:16

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '22 Jan 2021'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:43:48

US3192291

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:16

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Placebo (Placebo)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:43:48

US3192291

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:16

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Placebo (Placebo)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:43:48

US3192291

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:16

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Placebo (Placebo)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:43:48

US3192291

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:16

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:43:48

US3192291
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:16

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '1'	System	22 Jan 2021 23:43:48

US3192291
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:40:16
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '1'	System	22 Jan 2021 23:43:48

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '61' in	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '153' lb	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '28.96954'	System	22 Jan 2021 23:44:26
DataPoint set to visible.	System	22 Jan 2021 23:43:48

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '61' in	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '153' lb	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

US3192291
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '28.96954'	System	22 Jan 2021 23:44:26
DataPoint set to visible.	System	22 Jan 2021 23:43:48

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User accepted default value 'Pre-Dose (PREDOSE)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '22 Jan 2021'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

FDA-CBER-2022-1614-0409429

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '08:41'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

FDA-CBER-2022-1614-0409430

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '22 Jan 2021 08:41'	System	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '97.7' F	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Oral (Oral)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '63'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'bpm'	System	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '14'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'breaths/min'	System	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '131'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mmHg'	System	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '91'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

US3192291

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mmHg'	System	22 Jan 2021 23:44:26

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:40:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '61' in	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '153' lb	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:44:26

FDA-CBER-2022-1614-0409444

US3192291

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '28.96954'	System	22 Jan 2021 23:44:26
DataPoint set to visible.	System	22 Jan 2021 23:43:48

US3192291

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User accepted default value 'Post-Dose (POSTDOSE)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:10

US3192291

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:10

US3192291

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '22 Jan 2021'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:10

US3192291

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '09:42'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:10

US3192291

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '22 Jan 2021 09:42'	System	22 Jan 2021 23:45:10

US3192291

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '98.3' F	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:10

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Oral (Oral)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:10

FDA-CBER-2022-1614-0409452

US3192291

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:10

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '58'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:10

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'bpm'	System	22 Jan 2021 23:45:10

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:16

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '14'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:10

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'breaths/min'	System	22 Jan 2021 23:45:10

US3192291

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '132'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:10

US3192291

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mmHg'	System	22 Jan 2021 23:45:10

US3192291

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '84'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:10

US3192291

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mmHg'	System	22 Jan 2021 23:45:10

US3192291
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:31

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '22 Jan 2021'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:31

Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:40

FDA-CBER-2022-1614-0409464

US3192291

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:40

US3192291

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

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)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:40

US3192291

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mRNA-1273'	System	22 Jan 2021 23:45:40
DataPoint set to visible.	System	22 Jan 2021 23:43:48

US3192291

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '22 Jan 2021'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:40

Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '09:07'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:40

US3192291
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '22 Jan 2021 09:07'	System	22 Jan 2021 23:45:40

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Right Arm (RIGHT ARM)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:40

FDA-CBER-2022-1614-0409471

Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'ONCE'	System	22 Jan 2021 23:45:40

US3192291

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 23:45:40

Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:16
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:48

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '22 Jan 2021'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:48

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '08:57'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:48

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '22 Jan 2021 08:57'	System	22 Jan 2021 23:45:48

FDA-CBER-2022-1614-0409477

US3192291

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:40:16

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:54

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '22 Jan 2021'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:54

FDA-CBER-2022-1614-0409479

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '08:53'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:54

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '22 Jan 2021 08:53'	System	22 Jan 2021 23:45:54

FDA-CBER-2022-1614-0409481

US3192291

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

Form: Continuing

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	22 Jan 2021 23:45:56

US3192291
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '1'	System	22 Jan 2021 23:45:56

Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 23:52:54

US3192291

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered '1 Feb 2021'	(b) (4), (b) (6)	01 Feb 2021 23:52:54

US3192291
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 23:52:54

US3192291
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 23:52:54

US3192291

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 23:52:59

US3192291
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '1'	System	01 Feb 2021 23:52:59

US3192291
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '1'	System	01 Feb 2021 23:52:59
DataPoint set to visible.	System	01 Feb 2021 23:52:59

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 17:01:01

FDA-CBER-2022-1614-0409491

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '19 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 17:01:01

US3192291
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Feb 2021 17:01:01

US3192291
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'OLD29'	System	19 Feb 2021 17:01:01

US3192291
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User accepted default value 'Pre-Dose (PREDOSE)'		19 Feb 2021 17:01:53

Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 17:01:53

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered '19 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 17:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered '08:41'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:01:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '19 Feb 2021 08:41'	System	19 Feb 2021 17:01:53

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '97.4' F	(b) (4), (b) (6)	19 Feb 2021 17:01:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Feb 2021 17:01:53

FDA-CBER-2022-1614-0409501

US3192291
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:01:53

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '84'	(b) (4), (b) (6)	19 Feb 2021 17:01:53

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'bpm'	System	19 Feb 2021 17:01:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered '14'	(b) (4), (b) (6)	19 Feb 2021 17:01:53

Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:40:16

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'breaths/min'	System	19 Feb 2021 17:01:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '116'	(b) (4), (b) (6)	19 Feb 2021 17:01:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mmHg'	System	19 Feb 2021 17:01:53

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '79'	(b) (4), (b) (6)	19 Feb 2021 17:01:53

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mmHg'	System	19 Feb 2021 17:01:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User accepted default value 'Post-Dose (POSTDOSE)'		19 Feb 2021 17:02:44

FDA-CBER-2022-1614-0409511

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 17:02:44

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:02:44

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '09:42'	(b) (4), (b) (6)	19 Feb 2021 17:02:44

US3192291
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:16
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '19 Feb 2021 09:42'	System	19 Feb 2021 17:02:44

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '97.9' F	(b) (4), (b) (6)	19 Feb 2021 17:02:44

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Feb 2021 17:02:44

US3192291
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:40:16
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:02:44

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '62'	(b) (4), (b) (6)	19 Feb 2021 17:02:44

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'bpm'	System	19 Feb 2021 17:02:44

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered '14'	(b) (4), (b) (6)	19 Feb 2021 17:02:44

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'breaths/min'	System	19 Feb 2021 17:02:44

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '117'	(b) (4), (b) (6)	19 Feb 2021 17:02:44

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mmHg'	System	19 Feb 2021 17:02:44

US3192291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:16

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '86'	(b) (4), (b) (6)	19 Feb 2021 17:02:44

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mmHg'	System	19 Feb 2021 17:02:44

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 17:02:52

US3192291

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:02:52

US3192291
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 17:03:13

US3192291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:03:13

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)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:03:13

US3192291
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mRNA-1273'	System	19 Feb 2021 17:03:13
DataPoint set to visible.	System	01 Feb 2021 23:52:59

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
	(b) (4)	
User entered '19 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 17:03:13

US3192291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:16

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '09:10'	(b) (4), (b) (6)	19 Feb 2021 17:03:13

US3192291
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '19 Feb 2021 09:10'	System	19 Feb 2021 17:03:13

US3192291
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	19 Feb 2021 17:05:42
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	19 Feb 2021 17:05:42
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:05:42
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	19 Feb 2021 17:03:13
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	19 Feb 2021 17:03:13

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'ONCE'	System	19 Feb 2021 17:03:13

FDA-CBER-2022-1614-0409537

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Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:40:16
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 17:03:13

US3192291

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 17:03:19

US3192291

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:16

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '1'	System	19 Feb 2021 17:03:19

US3192291
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:03:05
User closed query 'Data is required. Please complete.' (Site from System).		26 Mar 2021 10:37:31
Query 'Data is required. Please complete.' answered with 'data entry error' (Site from System).		19 Mar 2021 20:23:20
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Mar 2021 20:22:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 20:22:56
User entered 'Yes (Y)'		19 Mar 2021 20:22:20

US3192291
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:41
User entered '1 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 21:03:05
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Mar 2021 20:22:56
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	19 Mar 2021 20:22:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 20:22:56
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Mar 2021 20:22:20
User entered '1 Feb 2021'	(b) (4), (b) (6)	19 Mar 2021 20:22:20

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:41
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 21:03:05
User entered empty; reason for change Data Entry Error		19 Mar 2021 20:22:56
User entered 'Contact Made (CONTACT MADE)'		19 Mar 2021 20:22:20

US3192291
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:40:16
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:41
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 20:22:20

Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:23:02

US3192291
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:40:16
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '1'	System	19 Mar 2021 20:23:02

US3192291
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:40:16

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:23:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:23:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Mar 2021 20:23:36

FDA-CBER-2022-1614-0409549

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'OLD57'	System	19 Mar 2021 20:23:36

FDA-CBER-2022-1614-0409550

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:24:26

FDA-CBER-2022-1614-0409551

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:24:26

FDA-CBER-2022-1614-0409552

US3192291
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '10:50'	(b) (4), (b) (6)	19 Mar 2021 20:24:26

US3192291
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '19 Mar 2021 10:50'	System	19 Mar 2021 20:24:26

US3192291
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '98.7' F	(b) (4), (b) (6)	19 Mar 2021 20:24:26

US3192291

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Mar 2021 20:24:26

US3192291

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 20:24:26

US3192291

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '69'	(b) (4), (b) (6)	19 Mar 2021 20:24:26

US3192291
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'bpm'	System	19 Mar 2021 20:24:26

US3192291
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '12'	(b) (4), (b) (6)	19 Mar 2021 20:24:26

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'breaths/min'	System	19 Mar 2021 20:24:26

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '135'	(b) (4), (b) (6)	19 Mar 2021 20:24:26

US3192291
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mmHg'	System	19 Mar 2021 20:24:26

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '82'	(b) (4), (b) (6)	19 Mar 2021 20:24:26

Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:40:16
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered 'mmHg'	System	19 Mar 2021 20:24:26

US3192291

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:16

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45

US3192291

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:24:36

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:16

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:24:36

Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:40:16

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:24:52

US3192291

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 15:18:38
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:24:52

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 15:18:38
User entered '10:58'	(b) (4), (b) (6)	19 Mar 2021 20:24:52

US3192291

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:49:45
User entered '19 Mar 2021 10:58'	System	19 Mar 2021 20:24:52

US3192291
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:40:16

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:30
User signature succeeded.	John McGettigan (b) (4) (b) (4)	12 Apr 2021 17:53:54
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 10:41:39
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 10:41:25
User closed query 'Per DM CLR: Per Day 92 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).		12 Apr 2021 10:41:23
Query 'Per DM CLR: Per Day 92 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'patient reported f/u, no changes noted ' (Site from DM).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:11:44

US3192291
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:40:16
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'patient reported f/u' (Site from DM).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:11:34
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:08:14
User opened query 'Per DM CLR: Per Day 92 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 15:44:41
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 13:40:40

US3192291

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:40:16

Did the participant experience any adverse events?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:11:34
User entered 'Yes (Y)' reason for change: Data Entry Error		13 Nov 2020 22:02:51
User entered 'No (N)' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:22:22
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:22:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

AEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:02:58
Reviewed for Safety.		16 Nov 2020 22:11:36
Un-reviewed for Safety.		16 Nov 2020 22:11:32
Reviewed for Safety.		16 Nov 2020 22:11:28
User entered 'USA-US097-2020-mRNA-1273-P301000004'	System	16 Nov 2020 22:11:20
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 22:11:20

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:02:52
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Clostridia infections, PT: Clostridium difficile colitis, LLT: C.difficile colitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 23:11:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 23:11:40
Data point term sent to Coder	System	13 Nov 2020 22:06:21
User entered 'C-Diff - Colitiis'	(b) (4), (b) (6)	13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:02:50
User entered 'Yes (Y)'		13 Nov 2020 22:06:18

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:02:47
User entered 'No (N)'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:02:45
User entered 'No (N)'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:02:43
User entered '2 Nov 2020'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:02:42
User entered empty.		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:02:39
User entered 'No (N)'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:02:37
User entered '10 Nov 2020'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:02:35
User entered empty.		13 Nov 2020 22:06:18

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Severity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:02:30
User entered 'Grade 4 (Grade 4)'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:02:32
User entered 'Yes (Y)'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:03:03
User entered '0'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:03:05
User entered '0'		13 Nov 2020 22:06:18

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:03:07
User entered '1'		13 Nov 2020 22:06:18

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:03:09
User entered '2 Nov 2020'		13 Nov 2020 22:06:18

FDA-CBER-2022-1614-0409594

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:03:10
User entered '10 Nov 2020'		13 Nov 2020 22:06:18

US3192291
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:03:13
User entered 'Yes (Y)'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:03:15
User entered '3'		13 Nov 2020 22:06:18

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:03:20
User entered '0'		13 Nov 2020 22:06:18

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:03:23
User entered '0'		13 Nov 2020 22:06:18

FDA-CBER-2022-1614-0409599

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:03:25
User entered '0'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:03:32
User entered 'Not Related (NOT RELATED)'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:19:56
User closed query 'PV Query: Since the subject received two doses of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).		26 Mar 2021 19:49:00
Query 'PV Query: Since the subject received two doses of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'updated' (Site from Safety).		25 Mar 2021 16:17:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error		25 Mar 2021 16:17:24
User opened query 'PV Query: Since the subject received two doses of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).		09 Mar 2021 20:14:26
User closed query 'Per CDM: Previous query was raised in error. Please review/reinstate previous response 'Not Applicable' per CCG's page 51, as AE started after date of last dose (12-SEP-2020). Thank you' (Site from DM).		04 Mar 2021 16:32:29
Query 'Per CDM: Previous query was raised in error. Please review/reinstate previous response 'Not Applicable' per CCG's page 51, as AE started after date of last dose (12-SEP-2020). Thank you' answered with 'updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	02 Mar 2021 21:58:37
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	02 Mar 2021 21:52:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	02 Mar 2021 21:52:19
User opened query 'Per CDM: Previous query was raised in error. Please review/reinstate previous response 'Not Applicable' per CCG's page 51, as AE started after date of last dose (12-SEP-2020). Thank you' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 14:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 14:55:27
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	Yvonne De Los Reyes (b) (4)	16 Feb 2021 18:44:30
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:08:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:35:31
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:25:47
User entered 'Not Applicable (NOT APPLICABLE)'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User closed query 'PV Query: As the last dose of study drug was given on 12 Sep 2020, please update the action taken with study drug from none to not applicable' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 18:00:04
Query 'PV Query: As the last dose of study drug was given on 12 Sep 2020, please update the action taken with study drug from none to not applicable' answered with 'updated' (Site from Safety).	Yvonne De Los Reyes (b) (4)	16 Feb 2021 18:44:56
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:08:15
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:35:31
User opened query 'PV Query: As the last dose of study drug was given on 12 Sep 2020, please update the action taken with study drug from none to not applicable' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:12:10
User entered 'None (NONE)'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:26:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #16 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:21:12
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #16 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 21:50:48
DataPoint Un-verified.		06 Apr 2021 21:50:25
User entered '0' reason for change: Data Entry Error		06 Apr 2021 21:50:25
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #16 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).		03 Apr 2021 11:36:51
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:20:03
DataPoint Un-verified.		25 Mar 2021 16:17:24
User entered '1' reason for change: Data Entry Error		25 Mar 2021 16:17:24
DataPoint Verified.		04 Feb 2021 18:08:18
User entered '0'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:25:57
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 21:50:25
User entered '1' reason for change: Data Entry Error		06 Apr 2021 21:50:25
DataPoint Verified.		30 Mar 2021 19:20:05
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		25 Mar 2021 21:04:44
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 16:17:56
User entered '0' reason for change: Data Entry Error		25 Mar 2021 16:17:24
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		21 Nov 2020 15:35:14
User entered '1'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:20:07
User entered '0'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:08:43
DataPoint Un-verified.		04 Feb 2021 18:08:41
DataPoint Verified.		04 Feb 2021 18:04:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		13 Nov 2020 22:06:18

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:09:13
User entered empty.		13 Nov 2020 22:06:18

US3192291
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 14:23:45
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).		03 May 2021 14:23:42
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).		03 May 2021 14:23:38
User closed query 'PV Query: Subject spent three days in intensive care unit. Did subject experience any complications secondary to C. difficile infection? If so, please provide details and consider reporting additional SAEs accordingly. ' (Site from Safety).		03 May 2021 14:23:35
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'records sent ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 20:13:34
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'summary emailed over ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 20:13:00

US3192291
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'any treatment received while in hospital has already been noted in con med and con procedures page. ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 19:16:57
Query 'PV Query: Subject spent three days in intensive care unit. Did subject experience any complications secondary to C. difficile infection? If so, please provide details and consider reporting additional SAEs accordingly. ' answered with 'no complications secondary to c. diff while in icu' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 19:11:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:26:38
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		15 Apr 2021 14:43:10
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).		15 Apr 2021 14:43:03
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).		15 Apr 2021 14:42:57
User opened query 'PV Query: Subject spent three days in intensive care unit. Did subject experience any complications secondary to C. difficile infection? If so, please provide details and consider reporting additional SAEs accordingly. ' (Site from Safety).		15 Apr 2021 14:42:50

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:36:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).		09 Apr 2021 13:36:39
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		09 Apr 2021 13:36:36
User closed query 'PV Query: Subject spent three days in intensive care unit. Did subject experience any complications secondary to C. difficile infection? If so, please provide details and consider reporting additional SAEs accordingly.' (Site from Safety).		08 Apr 2021 16:04:52
User closed query 'PV Query: Please provide symptoms that led to hospitalization.' (Site from Safety).		08 Apr 2021 14:23:33
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
Query 'PV Query: Subject spent three days in intensive care unit. Did subject experience any complications secondary to C. difficile infection? If so, please provide details and consider reporting additional SAEs accordingly.' answered with 'patient was diagnosed with hyponatremia and vomiting, secondary to c-diff. will update AE page ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:40:03
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:36:36

US3192291
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
User entered 'PATIENT REPORTED TO CLINIC HAVING COVID LIKE SYMPTOMS - COVID TEST NEGATIVE. ADMITTED TO HOSPITAL AND SENT HOME WITH ANTIBIOTICS. symptoms reported were nausea, vomiting, diarrhea, and fevers. Reason site did an illness visit.' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:36:36
Query 'PV Query: Please provide symptoms that led to hospitalization.' answered with 'diarrhea, nausea, vomiting, and fevers ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:35:40
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'will update' (Site from Safety).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:34:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' answered with 'will include in discharge summary when submitted ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:33:57
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records received, will send discharge summary with identifiers redacted ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:31:15
Query 'PV Query: subject was on Macrobid for UTI since 13 AUG 2020. Plese provide Macrobid stop date.' canceled (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 21:22:55
DataPoint Verified.		04 Feb 2021 18:09:12
User opened query 'PV Query: subject was on Macrobid for UTI since 13 AUG 2020. Plese provide Macrobid stop date.' (Site from Safety).		23 Nov 2020 18:13:32

US3192291
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Subject spent three days in intensive care unit. Did subject experience any complications secondary to C. difficile infection? If so, please provide details and consider reporting additional SAEs accordingly.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:13:13
User opened query 'PV Query: Please provide symptoms that led to hospitalization.' (Site from Safety).		23 Nov 2020 18:12:47
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		23 Nov 2020 18:12:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).		23 Nov 2020 18:12:29
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		23 Nov 2020 18:12:20
User entered 'patient reported to clinic having covid like symptoms - Covid test negative. Admitted to hospital and sent home with antibiotics.'		13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 22:06:18

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 00:16:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 00:16:14
Data point term sent to Coder	System	02 Feb 2021 13:44:51
User entered 'rash and itching from norvasc'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:16
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '14 Dec 2020'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
User entered empty.	System	02 Feb 2021 13:44:45

US3192291
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	02 Feb 2021 13:44:55
User entered '09 Jan 2021' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:55
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	02 Feb 2021 13:44:45
User entered '09 Jan 2020'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

FDA-CBER-2022-1614-0409628

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
User entered empty.	System	02 Feb 2021 13:44:45

US3192291
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

FDA-CBER-2022-1614-0409632

Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:16
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

FDA-CBER-2022-1614-0409633

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

FDA-CBER-2022-1614-0409638

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:44:43
	(b) (4)	
User entered '0'	Yvonne De Los Reyes	02 Feb 2021 13:44:45
	(b) (4)	

FDA-CBER-2022-1614-0409640

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

FDA-CBER-2022-1614-0409642

US3192291
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:16
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '1'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

FDA-CBER-2022-1614-0409649

US3192291
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
DataPoint Verified.		23 Apr 2021 01:20:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
User entered '0'	System	02 Feb 2021 13:44:45

US3192291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25
User entered '1'	System	02 Feb 2021 13:44:45

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:25

US3192291
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 00:16:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 00:16:05
Data point term sent to Coder	System	26 Feb 2021 00:15:03
User entered 'covid-like illness'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '27 Oct 2020'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 00:14:48

US3192291
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '10 Nov 2020'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 00:14:48

US3192291
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

FDA-CBER-2022-1614-0409669

Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

FDA-CBER-2022-1614-0409671

US3192291
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

FDA-CBER-2022-1614-0409676

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Not Related (NOT RELATED)'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Not Related (NOT RELATED)'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Not Applicable (NOT APPLICABLE)'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '1'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered '0'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:21:26
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:44:43
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Feb 2021 00:14:48

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 00:14:48

US3192291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 00:14:48

Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:40:16
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 02:34:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 02:34:38
Data point term sent to Coder	System	08 Apr 2021 01:51:16
User entered 'Worsening Hypertension'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

FDA-CBER-2022-1614-0409691

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:20:28
Signature has been broken.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:42:23
User entered '09 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:42:23
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '01 Nov 2020'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
User entered empty.	System	08 Apr 2021 01:50:36

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:20:28
Signature has been broken.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:42:23
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:42:23
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

FDA-CBER-2022-1614-0409696

US3192291
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:40:16
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:20:28
Signature has been broken.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:42:23
User entered '10 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:42:23
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

FDA-CBER-2022-1614-0409698

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
User entered empty.	System	08 Apr 2021 01:50:36

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:40:16
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:40:16
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:40:16
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

FDA-CBER-2022-1614-0409713

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '1'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
	(b) (4)	
User entered '0'	Yvonne De Los Reyes	08 Apr 2021 01:50:36
	(b) (4)	

US3192291
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:40:16
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:20:28
Signature has been broken.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:42:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:42:23
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

FDA-CBER-2022-1614-0409718

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
DataPoint Verified.		23 Apr 2021 01:20:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:50:36

FDA-CBER-2022-1614-0409720

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
User entered '0'	System	08 Apr 2021 01:50:36

US3192291

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39
User entered '1'	System	08 Apr 2021 01:50:36

Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:39

Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 02:50:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 02:50:07
Data point term sent to Coder	System	08 Apr 2021 02:03:18
User entered 'hyponatremia'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:59
Signature has been broken.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:43:02
User entered '03 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:43:02
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '17 Nov 2020'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
User entered empty.	System	08 Apr 2021 02:02:53

US3192291
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:59
Signature has been broken.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:43:02
User entered '08 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:43:02
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '28 Nov 2020'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
User entered empty.	System	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

FDA-CBER-2022-1614-0409745

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

FDA-CBER-2022-1614-0409749

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

FDA-CBER-2022-1614-0409750

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '1'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

FDA-CBER-2022-1614-0409755

US3192291
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
DataPoint Verified.		23 Apr 2021 01:26:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:02:53

US3192291

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
User entered '0'	System	08 Apr 2021 02:02:53

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33
User entered '1'	System	08 Apr 2021 02:02:53

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:33

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53

US3192291
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:40:16
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 02:50:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 02:50:15
Data point term sent to Coder	System	08 Apr 2021 02:04:19
User entered 'Vomiting'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
Signature has been broken.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 19:06:47
User entered '03 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 19:06:47
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '17 Nov 2020'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User entered empty.	System	08 Apr 2021 02:03:34

US3192291
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
Signature has been broken.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 19:06:47
User entered '05 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 19:06:47
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '28 Nov 2020'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:40:16

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User entered empty.	System	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
	(b) (4)	
User entered empty.	Yvonne De Los Reyes	08 Apr 2021 02:03:34
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
Signature has been broken.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 19:23:29
User entered '0' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 19:23:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '1'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
Signature has been broken.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 19:23:29
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 19:23:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User entered '0'	System	08 Apr 2021 02:03:34

US3192291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53
User entered '1'	System	08 Apr 2021 02:03:34

Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:53

US3192291
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:40:16
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28

US3192291
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:40:16
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:58:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:58:54
Data point term sent to Coder	System	21 Apr 2021 18:41:51
User entered 'sore arm post injection'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

FDA-CBER-2022-1614-0409798

US3192291
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '22 Jan 2021'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	22 Apr 2021 18:52:45
Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System).	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:08
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Apr 2021 18:41:02
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User entered empty.	System	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:40:16
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '22 Jan 2021'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	22 Apr 2021 18:52:47
Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System).	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:14
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Apr 2021 18:41:02
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User entered empty.	System	21 Apr 2021 18:41:02

Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:40:16

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

FDA-CBER-2022-1614-0409808

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Related (RELATED)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '1'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:41:02

US3192291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User entered '0'	System	21 Apr 2021 18:41:02

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28
User entered '0'	System	21 Apr 2021 18:41:02

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:28

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 03:08:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 03:08:52
Data point term sent to Coder	System	08 Apr 2021 02:19:21
User entered 'Acute Renal Failure'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

FDA-CBER-2022-1614-0409833

US3192291
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

FDA-CBER-2022-1614-0409835

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:39
Signature has been broken.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:07:19
User entered '03 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:07:19
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '28 Oct 2020'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

FDA-CBER-2022-1614-0409838

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered empty.	System	08 Apr 2021 02:18:56

US3192291
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:39
Signature has been broken.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:07:19
User entered '10 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:07:19
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
User entered '05 Nov 2020'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered empty.	System	08 Apr 2021 02:18:56

US3192291
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

FDA-CBER-2022-1614-0409845

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

FDA-CBER-2022-1614-0409848

US3192291
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

FDA-CBER-2022-1614-0409857

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

FDA-CBER-2022-1614-0409858

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '1'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

FDA-CBER-2022-1614-0409861

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

FDA-CBER-2022-1614-0409862

US3192291
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
DataPoint Verified.		23 Apr 2021 01:24:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:18:56

US3192291

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '0'	System	08 Apr 2021 02:18:56

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '1'	System	08 Apr 2021 02:18:56

US3192291
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 03:10:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 03:10:22
Data point term sent to Coder	System	08 Apr 2021 02:24:23
User entered 'gastroenteritis'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:50
Signature has been broken.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:09:21
User entered '03 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:09:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '28 Oct 2020'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
User entered empty.	System	08 Apr 2021 02:23:57

US3192291
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:50
Signature has been broken.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:09:21
User entered '10 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:09:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '05 Nov 2020'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

FDA-CBER-2022-1614-0409878

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
User entered empty.	System	08 Apr 2021 02:23:57

US3192291
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:50
Signature has been broken.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:09:21
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:09:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

FDA-CBER-2022-1614-0409881

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
User entered '0'	(b) (4) Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

FDA-CBER-2022-1614-0409891

US3192291
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '1'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
DataPoint Verified.		23 Apr 2021 01:27:50
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 02:23:57

FDA-CBER-2022-1614-0409900

US3192291
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:40:16
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
User entered '0'	System	08 Apr 2021 02:23:57

US3192291

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24
User entered '1'	System	08 Apr 2021 02:23:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:24

Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 03:47:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 03:47:14
Data point term sent to Coder	System	08 Apr 2021 03:09:45
User entered 'fatigue'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

FDA-CBER-2022-1614-0409907

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '12 Sep 2020'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User closed query 'Data is required. Please provide.' (Site from System).		19 Apr 2021 21:23:02
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:41
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Apr 2021 03:09:28
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User entered empty.	System	08 Apr 2021 03:09:28

FDA-CBER-2022-1614-0409911

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

FDA-CBER-2022-1614-0409912

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '19 Sep 2020'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User closed query 'Data is required. Please provide.' (Site from System).		19 Apr 2021 21:23:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:46
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Apr 2021 03:09:28
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User entered empty.	System	08 Apr 2021 03:09:28

FDA-CBER-2022-1614-0409915

US3192291
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
User entered empty.	(b) (4) Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 03:11:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 03:11:15
User entered 'Related (RELATED)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:11:15
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 03:09:28
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '1'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

US3192291
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:09:28

Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:40:16
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User entered '0'	System	08 Apr 2021 03:09:28

US3192291

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38
User entered '0'	System	08 Apr 2021 03:09:28

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:30:38

US3192291
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:40:16
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55

US3192291
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:11:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:11:57
Data point term sent to Coder	System	22 Apr 2021 16:11:24
User entered 'Hypotension'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User entered empty.	System	22 Apr 2021 16:10:27

FDA-CBER-2022-1614-0409947

US3192291
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered 'No (N)'	Yvonne De Los Reyes	22 Apr 2021 16:10:27
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered '08 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User entered empty.	System	22 Apr 2021 16:10:27

US3192291
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:40:16
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:40:16
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 16:10:27
	(b) (4)	

US3192291
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:40:16
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:42
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User entered '0'	System	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55
User entered '1'	System	22 Apr 2021 16:10:27

US3192291

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:15:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:11:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:11:59
Data point term sent to Coder	System	22 Apr 2021 16:11:24
User entered 'shortness of breath'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:40:16
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User entered empty.	System	22 Apr 2021 16:11:04

FDA-CBER-2022-1614-0409983

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered 'No (N)'	Yvonne De Los Reyes	22 Apr 2021 16:11:04
	(b) (4)	

US3192291
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:40:16
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered '08 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User entered empty.	System	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:40:16
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

FDA-CBER-2022-1614-0409992

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

FDA-CBER-2022-1614-0409995

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:40:16
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

FDA-CBER-2022-1614-0410004

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

US3192291
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:13
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:11:04

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User entered '0'	System	22 Apr 2021 16:11:04

FDA-CBER-2022-1614-0410009

US3192291

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14
User entered '1'	System	22 Apr 2021 16:11:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39

US3192291
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 16:17:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 16:17:56
Data point term sent to Coder	System	22 Apr 2021 16:17:33
User entered 'fever'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered '29 Oct 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User entered empty.	System	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:40:16
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered '04 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User entered empty.	System	22 Apr 2021 16:17:07

US3192291
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:40:16
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:40:16
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered '1'	Yvonne De Los Reyes	22 Apr 2021 16:17:07
	(b) (4)	

US3192291
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:40:16
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:23:38
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User entered '0'	System	22 Apr 2021 16:17:07

US3192291

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39
User entered '1'	System	22 Apr 2021 16:17:07

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:16:39

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:24:03
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:30:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:30:01
Data point term sent to Coder	System	22 Apr 2021 16:28:42
User entered 'fatigue'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

FDA-CBER-2022-1614-0410050

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered '29 Oct 2020'	Yvonne De Los Reyes	22 Apr 2021 16:28:17
	(b) (4)	

US3192291
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User entered empty.	System	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered '04 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

FDA-CBER-2022-1614-0410057

US3192291
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User entered empty.	System	22 Apr 2021 16:28:17

US3192291
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

FDA-CBER-2022-1614-0410074

US3192291
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

FDA-CBER-2022-1614-0410076

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:24:03
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User entered '0'	System	22 Apr 2021 16:28:17

US3192291

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59
User entered '1'	System	22 Apr 2021 16:28:17

Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:21:59

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:32:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:32:03
Data point term sent to Coder	System	22 Apr 2021 16:31:46
User entered 'Diarrhea'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User entered empty.	System	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User entered empty.	System	22 Apr 2021 16:31:29

US3192291
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

FDA-CBER-2022-1614-0410099

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
User entered empty.	(b) (4) Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

FDA-CBER-2022-1614-0410103

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

FDA-CBER-2022-1614-0410110

US3192291
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:40:16
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:31:29

US3192291

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User entered '0'	System	22 Apr 2021 16:31:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13
User entered '1'	System	22 Apr 2021 16:31:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:13

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:34:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:34:17
Data point term sent to Coder	System	22 Apr 2021 16:32:49
User entered 'Nausea/vomiting'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered 'No (N)'	Yvonne De Los Reyes	22 Apr 2021 16:32:07
	(b) (4)	

FDA-CBER-2022-1614-0410123

US3192291
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:40:16
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered '28 Oct 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User entered empty.	System	22 Apr 2021 16:32:07

FDA-CBER-2022-1614-0410127

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User entered empty.	System	22 Apr 2021 16:32:07

US3192291
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 16:32:07
	(b) (4)	

US3192291
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:40:16
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:40:16
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered empty.	Yvonne De Los Reyes	22 Apr 2021 16:32:07
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 16:32:07
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered '1'	Yvonne De Los Reyes	22 Apr 2021 16:32:07
	(b) (4)	

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

FDA-CBER-2022-1614-0410149

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:26:26
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:32:07

US3192291
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:40:16
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User entered '0'	System	22 Apr 2021 16:32:07

US3192291

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37
User entered '1'	System	22 Apr 2021 16:32:07

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:37

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Mental disorders NEC, PT: Mental status changes, LLT: Mental status changes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:34:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:34:50
Data point term sent to Coder	System	22 Apr 2021 16:34:15
User entered 'Altered Mental status'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

FDA-CBER-2022-1614-0410158

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered 'No (N)'	Yvonne De Los Reyes	22 Apr 2021 16:33:34
	(b) (4)	

FDA-CBER-2022-1614-0410160

Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User entered empty.	System	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered 'No (N)'	Yvonne De Los Reyes	22 Apr 2021 16:33:34
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered '05 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

FDA-CBER-2022-1614-0410165

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User entered empty.	System	22 Apr 2021 16:33:34

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

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EAB) (1725)

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered empty.	Yvonne De Los Reyes	22 Apr 2021 16:33:34
	(b) (4)	

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

FDA-CBER-2022-1614-0410177

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 16:33:34
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:27:25
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User entered '0'	System	22 Apr 2021 16:33:34

US3192291

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43
User entered '1'	System	22 Apr 2021 16:33:34

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25

US3192291

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:35:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:35:53
Data point term sent to Coder	System	22 Apr 2021 16:35:17
User entered 'Hypokalemia'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

FDA-CBER-2022-1614-0410194

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

FDA-CBER-2022-1614-0410198

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User entered empty.	System	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

FDA-CBER-2022-1614-0410201

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User entered empty.	System	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

FDA-CBER-2022-1614-0410220

US3192291

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:21
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:34:40

Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User entered '0'	System	22 Apr 2021 16:34:40

US3192291
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:40:16
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25
User entered '1'	System	22 Apr 2021 16:34:40

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:25

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:36:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:36:56
Data point term sent to Coder	System	22 Apr 2021 16:36:18
User entered 'worsening hypertension'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

FDA-CBER-2022-1614-0410230

Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

FDA-CBER-2022-1614-0410231

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered '09 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User entered empty.	System	22 Apr 2021 16:35:21

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User entered empty.	System	22 Apr 2021 16:35:21

FDA-CBER-2022-1614-0410239

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

FDA-CBER-2022-1614-0410247

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 16:35:21
	(b) (4)	

Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:28:47
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:35:21

US3192291

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User entered '0'	System	22 Apr 2021 16:35:21

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54
User entered '1'	System	22 Apr 2021 16:35:21

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:36:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:36:55
Data point term sent to Coder	System	22 Apr 2021 16:36:18
User entered 'Abdominal pain'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User entered empty.	System	22 Apr 2021 16:36:06

FDA-CBER-2022-1614-0410271

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User entered empty.	System	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

FDA-CBER-2022-1614-0410277

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

FDA-CBER-2022-1614-0410280

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

FDA-CBER-2022-1614-0410290

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:29:12
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:06

US3192291
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:40:16
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User entered '0'	System	22 Apr 2021 16:36:06

US3192291

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03
User entered '1'	System	22 Apr 2021 16:36:06

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:03

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:37:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:37:58
Data point term sent to Coder	System	22 Apr 2021 16:37:19
User entered 'hypotension'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered '07 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User entered empty.	System	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered '08 Nov 2020'	Yvonne De Los Reyes	22 Apr 2021 16:36:51
	(b) (4)	

Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User entered empty.	System	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

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Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes	22 Apr 2021 16:36:51
	(b) (4)	

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:22:40
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:36:51

US3192291
Folder: Adverse Events
Form: Adverse Events (21)
Generated On: 09 Jun 2021 15:40:16
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User entered '0'	System	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43
User entered '1'	System	22 Apr 2021 16:36:51

US3192291

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Tricuspid valvular disorders, PT: Tricuspid valve incompetence, LLT: Tricuspid regurgitation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 07:28:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 07:28:25
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
Data point term sent to Coder	System	22 Apr 2021 16:38:20
User entered 'Severe Tricuspid Valve Regurgitation'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered '09 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User entered empty.	System	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User entered empty.	System	22 Apr 2021 16:37:52

FDA-CBER-2022-1614-0410347

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

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US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered empty.	Yvonne De Los Reyes	22 Apr 2021 16:37:52
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered empty.	Yvonne De Los Reyes	22 Apr 2021 16:37:52
	(b) (4)	

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes	22 Apr 2021 16:37:52
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

FDA-CBER-2022-1614-0410362

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

FDA-CBER-2022-1614-0410366

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

FDA-CBER-2022-1614-0410367

US3192291
Folder: Adverse Events
Form: Adverse Events (22)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User entered '0'	System	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01
User entered '1'	System	22 Apr 2021 16:37:52

US3192291

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:01

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema, LLT: Edema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:39:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:39:55
Data point term sent to Coder	System	22 Apr 2021 16:39:26
User entered 'Edema'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

FDA-CBER-2022-1614-0410375

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered '09 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User entered empty.	System	22 Apr 2021 16:38:57

FDA-CBER-2022-1614-0410379

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User entered empty.	System	22 Apr 2021 16:38:57

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 16:38:57
	(b) (4)	

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

FDA-CBER-2022-1614-0410398

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:30:36
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:38:57

US3192291

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User entered '0'	System	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59
User entered '1'	System	22 Apr 2021 16:38:57

US3192291
Folder: Adverse Events
Form: Adverse Events (23)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:59

US3192291
Folder: Adverse Events
Form: Adverse Events (24)
Generated On: 09 Jun 2021 15:40:16
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Bladder spasm, LLT: Bladder spasm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:41:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 16:41:53
Data point term sent to Coder	System	22 Apr 2021 16:40:26
User entered 'Bladder spasms'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291
Folder: Adverse Events
Form: Adverse Events (24)
Generated On: 09 Jun 2021 15:40:16
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291
Folder: Adverse Events
Form: Adverse Events (24)
Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291
Folder: Adverse Events
Form: Adverse Events (24)
Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered '08 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User entered empty.	System	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered '09 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User entered empty.	System	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291
Folder: Adverse Events
Form: Adverse Events (24)
Generated On: 09 Jun 2021 15:40:16
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

FDA-CBER-2022-1614-0410422

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 16:40:03
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered empty.	Yvonne De Los Reyes	22 Apr 2021 16:40:03
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291
Folder: Adverse Events
Form: Adverse Events (24)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered empty.	Yvonne De Los Reyes	22 Apr 2021 16:40:03
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291
Folder: Adverse Events
Form: Adverse Events (24)
Generated On: 09 Jun 2021 15:40:16
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291
Folder: Adverse Events
Form: Adverse Events (24)
Generated On: 09 Jun 2021 15:40:16
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 16:40:03
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

FDA-CBER-2022-1614-0410438

Folder: Adverse Events
Form: Adverse Events (24)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291
Folder: Adverse Events
Form: Adverse Events (24)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:31:18
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 16:40:03

US3192291

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User entered '0'	System	22 Apr 2021 16:40:03

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59
User entered '1'	System	22 Apr 2021 16:40:03

FDA-CBER-2022-1614-0410442

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:19:59

US3192291
Folder: Adverse Events
Form: Adverse Events (25)
Generated On: 09 Jun 2021 15:40:16
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 18:01:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 18:01:16
Data point term sent to Coder	System	22 Apr 2021 17:48:13
User entered 'Mild hyponatremia'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291
Folder: Adverse Events
Form: Adverse Events (25)
Generated On: 09 Jun 2021 15:40:16
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291
Folder: Adverse Events
Form: Adverse Events (25)
Generated On: 09 Jun 2021 15:40:16
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered '24 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291
Folder: Adverse Events
Form: Adverse Events (25)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User entered empty.	System	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered '29 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

FDA-CBER-2022-1614-0410454

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User entered empty.	System	22 Apr 2021 17:47:59

US3192291
Folder: Adverse Events
Form: Adverse Events (25)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291
Folder: Adverse Events
Form: Adverse Events (25)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 17:47:59
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291
Folder: Adverse Events
Form: Adverse Events (25)
Generated On: 09 Jun 2021 15:40:16
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 17:47:59
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

FDA-CBER-2022-1614-0410473

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

US3192291
Folder: Adverse Events
Form: Adverse Events (25)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:32:10
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:47:59

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User entered '0'	System	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24
User entered '1'	System	22 Apr 2021 17:47:59

US3192291

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:20:24

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:58:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:58:05
Data point term sent to Coder	System	22 Apr 2021 17:56:22
User entered 'Vomiting'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '24 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User entered empty.	System	22 Apr 2021 17:55:27

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '29 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User entered empty.	System	22 Apr 2021 17:55:27

FDA-CBER-2022-1614-0410491

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

FDA-CBER-2022-1614-0410499

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291
Folder: Adverse Events
Form: Adverse Events (26)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:55:27

US3192291

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User entered '0'	System	22 Apr 2021 17:55:27

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29
User entered '1'	System	22 Apr 2021 17:55:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:18:29

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:13:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:13:06
Data point term sent to Coder	System	22 Apr 2021 18:11:50
User entered 'Irritable Bowel syndrome'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered '05 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:03
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	22 Apr 2021 18:11:03
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	22 Apr 2021 18:10:55
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

FDA-CBER-2022-1614-0410525

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered 'No (N)'	Yvonne De Los Reyes	22 Apr 2021 18:10:55
	(b) (4)	

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered empty.	Yvonne De Los Reyes	22 Apr 2021 18:10:55
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered '0'	Yvonne De Los Reyes	22 Apr 2021 18:10:55
	(b) (4)	

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16
Outcome

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (27)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:07
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:10:55

US3192291

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 18:10:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 18:10:55

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Loose stools - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:22:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:22:02
Data point term sent to Coder	System	22 Apr 2021 18:21:19
User entered 'loose stools'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '26 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User entered empty.	System	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '29 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User entered empty.	System	22 Apr 2021 18:20:49

FDA-CBER-2022-1614-0410561

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291
Folder: Adverse Events
Form: Adverse Events (28)
Generated On: 09 Jun 2021 15:40:16
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User entered '0'	System	22 Apr 2021 18:20:49

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35
User entered '1'	System	22 Apr 2021 18:20:49

US3192291

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:35

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Asthenia, LLT: Weakness generalized - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:23:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:23:02
Data point term sent to Coder	System	22 Apr 2021 18:22:25
User entered 'generalized weakness'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '24 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User entered empty.	System	22 Apr 2021 18:21:28

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '29 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User entered empty.	System	22 Apr 2021 18:21:28

FDA-CBER-2022-1614-0410597

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

FDA-CBER-2022-1614-0410598

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

FDA-CBER-2022-1614-0410602

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '1'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

FDA-CBER-2022-1614-0410617

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:28
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:21:28

US3192291

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 15:40:16

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User entered '0'	System	22 Apr 2021 18:21:28

US3192291
Folder: Adverse Events
Form: Adverse Events (29)
Generated On: 09 Jun 2021 15:40:16
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43
User entered '1'	System	22 Apr 2021 18:21:28

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:17:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:30
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:32:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACROBID [NITROFURANTOIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:35:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:35:54
Data point term sent to Coder	System	10 Sep 2020 20:34:53
User entered 'Macrobid'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:57:19
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'this has been updated as it is in the med hx and in the source and not a prophylaxis criteria ' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:51:57
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:51:41
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:50:13
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Urinary Tract Infection'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '100'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'twice daily (BID)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '13 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:51:41
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '19 Aug 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:51:41
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User entered '2'	System	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User entered '1'	System	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:28
User entered '804 (804)'	System	10 Sep 2020 20:34:24

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:36:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:36:45
Data point term sent to Coder	System	10 Sep 2020 20:35:58
User entered 'Spirolactone'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 22:51:23
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'its been updated as it is not am prophylaxis criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:32:35
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:32:08
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:51:54
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Hypertension'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '25'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User		Time (GMT)
User signature succeeded.	John McGettigan	(b) (4)	08 Apr 2021 12:36:18
	(b) (4)		
User entered 'mg (mg)'	Norma Barrientos	(b) (4)	10 Sep 2020 20:35:23
	(b) (4)		

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'once daily (QD)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

FDA-CBER-2022-1614-0410650

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'un UNK 1995'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User		Time (GMT)
User signature succeeded.	John McGettigan	(b) (4)	08 Apr 2021 12:36:18
	(b) (4)		
User entered '0'	Norma Barrientos	(b) (4)	10 Sep 2020 20:35:23
	(b) (4)		

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:35:23

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:35:23

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 20:35:23

FDA-CBER-2022-1614-0410658

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
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)	10 Sep 2020 20:37:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:37:45
Data point term sent to Coder	System	10 Sep 2020 20:37:01
User entered 'Metoprolol'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 22:51:35
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'its been updated as it is not am prophylaxis criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:33:05
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:32:44
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:49:53
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Hypertension'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '100'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'twice daily (BID)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'un UNK 1995'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4)	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 20:36:11

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:39:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:39:43
Data point term sent to Coder	System	10 Sep 2020 20:39:08
User entered 'Crestor'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 22:51:54
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'its been updated as it is not am prophylaxis criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:33:20
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:33:13
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:45:38
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Hypercholesterolemia'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '20'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'once daily (QD)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'un UNK 1990'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
	(b) (4)	
User entered '0'	Norma Barrientos (b) (4)	10 Sep 2020 20:38:18
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User		Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)		08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)		10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 20:38:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:40:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:40:45
Data point term sent to Coder	System	10 Sep 2020 20:40:11
User entered 'Meloxicam'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 22:52:09
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'its been updated as it is not am prophylaxis criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:33:39
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:33:32
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:49:33
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 18:55:23
Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' answered with 'patient did not specify ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 12:44:21
User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:22:53
User entered 'osteoarthritis'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '15'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

FDA-CBER-2022-1614-0410699

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'twice daily (BID)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

FDA-CBER-2022-1614-0410701

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'un UNK 1995'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 20:39:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE, PRODUCTSYNONYM: LAMICTAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 08:39:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 08:39:58
Data point term sent to Coder	System	10 Sep 2020 20:59:05
Data point term sent to Coder	System	10 Sep 2020 20:42:13
User entered 'Lamictal'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 22:52:21
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'its been updated as it is not am prophylaxis criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:33:57
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:33:50
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:49:03
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User		Time (GMT)
User signature succeeded.	John McGettigan	(b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'BIPLOAR Disorder' reason for change: Data Entry Error	Norma Barrientos	(b) (4) (b) (4)	10 Sep 2020 20:58:22
User entered 'Biploar'	Norma Barrientos	(b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '100'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'once daily (QD)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR RQ: Thank you for your response, however this conmed start date is prior to the start date, 1991, of the condition on MH eCRF. Please review and reconcile CM and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:02:21
Query 'Per DM CLR RQ: Thank you for your response, however this conmed start date is prior to the start date, 1991, of the condition on MH eCRF. Please review and reconcile CM and MH start dates as appropriate.' answered with 'START DATE OF MH BIPOLAR DISORDER HAS BEEN CORRECTED, WITH START YEAR 1990, PER SOURCE.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	03 Oct 2020 17:53:48
User opened query 'Per DM CLR RQ: Thank you for your response, however this conmed start date is prior to the start date, 1991, of the condition on MH eCRF. Please review and reconcile CM and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 18:58:36
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (1991). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).		01 Oct 2020 18:56:05
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (1991). Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'updated ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:02:49
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (1991). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:23:07
User entered 'un UNK 1990'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 20:41:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: CLOMIPRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: ANAFRANIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:59:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:59:45
Data point term sent to Coder	System	10 Sep 2020 20:59:05
Coding entries removed.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:58:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: CLOMIPRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: ANAFRANIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:45:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:45:43
Data point term sent to Coder	System	10 Sep 2020 20:44:27
User entered 'Anafranil'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 22:52:48
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'its been updated as it is not am prophylaxis criteria and it is updated in med hx and in source' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:35:59
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:34:07
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:45:57
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'BIPOLAR disorder' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:58:51
User entered 'Bipolar'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '25'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'other (OTHER)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Twice a week'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'un UNK 1995'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 20:43:43

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DEPAKOTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 21:00:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 21:00:44
Data point term sent to Coder	System	10 Sep 2020 21:00:07
Data point term sent to Coder	System	10 Sep 2020 20:45:32
User entered 'depakote'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:57:58
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'this has been updated as it is in the med hx and in the source' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:38:49
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:38:23
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:46:46
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

FDA-CBER-2022-1614-0410750

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'BIPOLAR DISORDER' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:59:30
User entered 'Bipolar II Disorder'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '125'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 18:56:30
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' answered with 'updated ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:04:12
User entered 'mg (mg)' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:04:02
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:23:33
User entered 'ug (ug)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'every other day (QOD)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'un UNK 1992'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User		Time (GMT)
User signature succeeded.	John McGettigan	(b) (4)	08 Apr 2021 12:36:18
	(b) (4)		
User entered 'Yes (Y)'	Norma Barrientos	(b) (4)	10 Sep 2020 20:44:39
	(b) (4)		

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 20:44:39

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:49:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:49:55
Data point term sent to Coder	System	10 Sep 2020 21:00:08
Data point term sent to Coder	System	10 Sep 2020 20:47:37
User entered 'gabapentin'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:58:11
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'this has been updated as it is in the med hx and in the source and no its not a prophylaxis criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:46:10
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:39:05
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:48:46
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'OBSESSIVE COMPULSIVE DISORDER/BIPOLAR disorder' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 21:00:07
User entered 'Obsessive compulsive disorder/bipolar II'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '100'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	10 Sep 2020 20:53:28
User entered 'other (OTHER)' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:53:28
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	10 Sep 2020 20:47:10
User entered 'once (ONCE)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'twice a week'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'un UNK 2015'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 20:47:10

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE HYDROCHLORIDE, PRODUCTSYNONYM: BUSPAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:50:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:50:43
Data point term sent to Coder	System	10 Sep 2020 20:49:41
User entered 'Buspar'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:58:23
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'this has been updated as it is in the med hx and in the source and not a prophylaxis criteria ' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:47:14
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:46:33
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:46:13
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Bipolar disorder'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '10'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User		Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)		08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)		10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'four times daily (QID)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'un UNK 2019'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

FDA-CBER-2022-1614-0410797

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '4'	System	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:49:25

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 20:49:25

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
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/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:51:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:51:50
Data point term sent to Coder	System	10 Sep 2020 20:50:42
User entered 'Hydrocodone/APAP'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:58:35
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'this has been updated as it is in the med hx and in the source and not a prophylaxis criteria ' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:48:05
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:47:42
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:48:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:00:19
Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' answered with 'patient did not specify ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:21:42
User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:23:54
User entered 'osteoarthritis'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '7.5/500'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'as needed (PRN)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'un UNK 2019'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 20:50:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:25:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 20:25:40
Data point term sent to Coder	System	29 Sep 2020 20:24:39
Coding entries removed.	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:23:53
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:52:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:52:45
Data point term sent to Coder	System	10 Sep 2020 20:51:46
User entered 'Estradiol'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:00:33
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:24:00
User entered 'Post Menopausal' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:23:53
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:24:10
User entered 'Hormone Replacement Therapy'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '1'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'once daily (QD)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'un UNK 1995'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 20:51:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE, PRODUCTSYNONYM: PROMETRIUM [PROGESTERONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:52:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:52:27
Data point term sent to Coder	System	29 Sep 2020 20:23:38
Coding entries removed.	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:23:23
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 08:18:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 08:18:58
Data point term sent to Coder	System	10 Sep 2020 20:52:50
User entered 'Prometrium'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:59:13
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'this has been updated as it is in the med hx and in the source and not a prophylaxis criteria ' (Site from DM).	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:49:55
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	24 Oct 2020 18:49:05
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 06:50:42
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:00:58
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:23:31
User entered 'Postmenopausal' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	29 Sep 2020 20:23:23
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:24:18
User entered 'Hormone Replacement Therapy'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '100'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'once daily (QD)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
	(b) (4)	
User entered empty.	Norma Barrientos (b) (4)	10 Sep 2020 20:52:30
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'un UNK 1995'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 20:52:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).		12 Apr 2021 08:04:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'AE term updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 01:49:18
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 05:19:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:57:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:57:42
Data point term sent to Coder	System	11 Jan 2021 21:41:42
User entered 'Norvasc'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:40:16
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Hypertension'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

FDA-CBER-2022-1614-0410859

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '2.5'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
User entered '2 Nov 2020'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
User entered '0'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '4 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	(b) (4), (b) (6)	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User entered '2'	System	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User entered '1'	System	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User entered '804 (804)'	System	11 Jan 2021 21:41:02

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 13:51:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 13:51:28
Data point term sent to Coder	System	02 Feb 2021 13:50:53
User entered 'Vancomycin'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'C-Diff'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '125'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'four times daily (QID)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered empty.	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User closed query 'Per CDM-RQ: The start date of the conmed is stop date of the corresponding AE. Kindly review start and stop date of Conmed and AE. Thank you.' (Site from DM).		16 Apr 2021 05:33:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	13 Apr 2021 15:08:31
Query 'Per CDM-RQ: The start date of the conmed is stop date of the corresponding AE. Kindly review start and stop date of Conmed and AE. Thank you.' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	12 Apr 2021 21:28:38
Signature has been broken.	maggie Tono (b) (4) (b) (4)	12 Apr 2021 21:28:25
User entered '2 Nov 2020' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	12 Apr 2021 21:28:25
User opened query 'Per CDM-RQ: The start date of the conmed is stop date of the corresponding AE. Kindly review start and stop date of Conmed and AE. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 10:40:35
User closed query 'Per DM CLR: Please review Con Med start date as this is the same as the stop date of the corresponding AE and continue to 20 NOV 2020. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 10:37:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
Query 'Per DM CLR: Please review Con Med start date as this is the same as the stop date of the corresponding AE and continue to 20 NOV 2020. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'these dates are correct' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 02:53:10
User opened query 'Per DM CLR: Please review Con Med start date as this is the same as the stop date of the corresponding AE and continue to 20 NOV 2020. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 18:47:38

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '0'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	13 Apr 2021 15:08:31
Signature has been broken.	maggie Tono (b) (4) (b) (4)	12 Apr 2021 21:28:25
User entered '10 Nov 2020' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	12 Apr 2021 21:28:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered '20 Nov 2020'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 12:36:18
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	02 Feb 2021 13:50:05

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User entered '4'	System	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User entered '1'	System	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:44
User entered '804 (804)'	System	02 Feb 2021 13:50:05

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:38:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:38:25
Data point term sent to Coder	System	21 Apr 2021 18:06:57
User entered 'norvasc'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered 'worsening hypertension'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered '2.5'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered 'twice daily (BID)'	Yvonne De Los Reyes	21 Apr 2021 18:06:42
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered '02 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered '0'	Yvonne De Los Reyes	21 Apr 2021 18:06:42
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered 'No (N)'	Yvonne De Los Reyes	21 Apr 2021 18:06:42
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered '04 Jan 2021'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:36
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:06:42

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User entered '2'	System	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User entered '1'	System	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:46
User entered '804 (804)'	System	21 Apr 2021 18:06:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:00:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:00:35
Data point term sent to Coder	System	21 Apr 2021 18:07:58
User entered 'Vancomycin'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered 'C.Diff colitis'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered '125'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered 'four times daily (QID)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered '20 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:37
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User entered '4'	System	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User entered '1'	System	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:49
User entered '804 (804)'	System	21 Apr 2021 18:07:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:42:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:42:18
Data point term sent to Coder	System	21 Apr 2021 18:08:59
User entered 'Ibuprofen'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered 'chills, fever'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered '400'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered 'as needed (PRN)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered '28 Oct 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered '29 Oct 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:38
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:17

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:40:16
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User entered empty.	System	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User entered empty.	System	21 Apr 2021 18:08:17

PRODUCTION RELEASE (v12.003
EAB) (1725)

3551 of 4019

FDA-CBER-2022-1614-0410946

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:55
User entered empty.	System	21 Apr 2021 18:08:17

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:39
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)	21 Apr 2021 19:42:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:42:17
Data point term sent to Coder	System	21 Apr 2021 18:08:59
User entered 'Tylenol'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered 'chills, fever'	Yvonne De Los Reyes	21 Apr 2021 18:08:56
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered '500'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered 'as needed (PRN)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered '28 Oct 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered '29 Oct 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:39
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User entered empty.	System	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User entered empty.	System	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:59
User entered empty.	System	21 Apr 2021 18:08:56

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:42:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:42:51
Data point term sent to Coder	System	21 Apr 2021 18:10:00
User entered 'Zofran'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered 'nausea/vomiting'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered '3'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered 'as needed (PRN)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered '01 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered '02 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:43
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User entered empty.	System	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User entered empty.	System	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User entered empty.	System	21 Apr 2021 18:09:42

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:02:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:02:38
Data point term sent to Coder	System	21 Apr 2021 18:11:01
User entered 'Zofran'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered 'Nausea/vomiting'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

PRODUCTION RELEASE (v12.003
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3591 of 4019

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered '4'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered 'once (ONCE)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered 'Intravenous (INTRAVENOUS)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:45
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User entered empty.	System	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User entered empty.	System	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:42
User entered empty.	System	21 Apr 2021 18:10:55

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, PRODUCT: ALL OTHER THERAPEUTIC PRODUCTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:58:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:58:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
Data point term sent to Coder	System	25 Apr 2021 14:55:15
Query 'CDM-Coding: The trade name NP Bolus can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	25 Apr 2021 14:54:50
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:48
User opened query 'CDM-Coding: The trade name NP Bolus can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:46:46
Data point term sent to Coder	System	21 Apr 2021 18:13:10
User entered 'NP Bolus'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered 'hydration/nausea/vomiting'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered '1000'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered 'mL (mL)'	Yvonne De Los Reyes	21 Apr 2021 18:12:27
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered 'once (ONCE)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

FDA-CBER-2022-1614-0411010

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:48
User entered 'No (N)'	Yvonne De Los Reyes	21 Apr 2021 18:12:27
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User entered empty.	System	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User entered empty.	System	21 Apr 2021 18:12:27

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User entered empty.	System	21 Apr 2021 18:12:27

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:24:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:24:58
Data point term sent to Coder	System	21 Apr 2021 18:13:11
User entered 'dextrose'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered 'dehydration'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered '1000'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered 'mL (mL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered 'as needed (PRN)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered 'Intravenous (INTRAVENOUS)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

FDA-CBER-2022-1614-0411032

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered '07 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:35:47
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User entered empty.	System	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User entered empty.	System	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:05
User entered empty.	System	21 Apr 2021 18:13:09

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:38:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:50:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:50:53
Data point term sent to Coder	System	21 Apr 2021 18:18:21
User entered 'Acetaminophen'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered 'Abdominal Pain'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered '500'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered 'four times daily (QID)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered '07 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:38:58
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User entered '4'	System	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User entered '1'	System	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:08
User entered '804 (804)'	System	21 Apr 2021 18:18:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: CLOMIPRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:50:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:50:56
Data point term sent to Coder	System	21 Apr 2021 18:19:22
User entered 'Clomipramine'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered 'OCD'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered '25'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered 'as needed (PRN)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered '09 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:00
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User entered empty.	System	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User entered empty.	System	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:12
User entered empty.	System	21 Apr 2021 18:19:18

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
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)	21 Apr 2021 19:51:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:51:08
Data point term sent to Coder	System	21 Apr 2021 18:21:25
User entered 'Heparin'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered 'prevention of blood clots'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered '1'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered 'mL (mL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered 'twice daily (BID)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:40:16
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered 'Subcutaneous (SUBCUTANEOUS)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered '09 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:01
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User entered '2'	System	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User entered '1'	System	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:15
User entered '804 (804)'	System	21 Apr 2021 18:20:44

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:11:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:11:55
Data point term sent to Coder	System	21 Apr 2021 18:23:30
User entered 'Ativan'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered 'Anxiety'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered '0.5'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered 'as needed (PRN)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered 'Intravenous (INTRAVENOUS)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered empty.	Yvonne De Los Reyes	21 Apr 2021 18:23:00
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered '09 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:03
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User entered empty.	System	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User entered empty.	System	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:18
User entered empty.	System	21 Apr 2021 18:23:00

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:02:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:02:49
Data point term sent to Coder	System	21 Apr 2021 18:24:33
User entered 'Amolodipine'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered 'Worsening hypertension'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered '5'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered 'once daily (QD)'	Yvonne De Los Reyes	21 Apr 2021 18:24:03
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered '08 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered '0'	Yvonne De Los Reyes	21 Apr 2021 18:24:03
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:04
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	21 Apr 2021 18:24:08
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	21 Apr 2021 18:24:03
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 18:24:03

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:51:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:51:58
Data point term sent to Coder	System	21 Apr 2021 18:25:36
User entered 'Lasix'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered 'Severe Tricuspid Regurgitation/edema'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered '20'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered '09 Nov 2020'	Yvonne De Los Reyes	21 Apr 2021 18:25:12
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered 'Yes (Y)'	Yvonne De Los Reyes	21 Apr 2021 18:25:12
	(b) (4)	

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:05
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 18:25:12

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:52:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:52:48
Data point term sent to Coder	System	21 Apr 2021 18:28:40
User entered 'magnesium sulfate'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered 'electrolyte replacement'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered '100'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered 'mL (mL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered 'as needed (PRN)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered 'Intravenous (INTRAVENOUS)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered '09 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:07
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:27:48

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:40:16
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User entered empty.	System	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User entered empty.	System	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:56
User entered empty.	System	21 Apr 2021 18:27:48

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: SOLIFENACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:12:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:12:53
Data point term sent to Coder	System	21 Apr 2021 18:28:40
User entered 'Solifenacin'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered 'Bladder spasms'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered '5'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

FDA-CBER-2022-1614-0411170

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered '09 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:52:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:39:08
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User entered '1'	System	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User entered '1'	System	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:00
User entered '804 (804)'	System	21 Apr 2021 18:28:30

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:38:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:38:06
Data point term sent to Coder	System	22 Apr 2021 17:36:48
User entered 'progesterone'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'post menopause'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '100'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'un UNK 2019'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 17:36:19

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:01:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:01:15
Data point term sent to Coder	System	22 Apr 2021 18:00:32
User entered 'Zofran'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'vomiting'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '8'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'three times daily (TID)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '24 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '29 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:00:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User entered '3'	System	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User entered '1'	System	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:11
User entered '804 (804)'	System	22 Apr 2021 18:00:14

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:42:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:42:43
Data point term sent to Coder	System	22 Apr 2021 18:02:37
User entered 'Potassium Chloride'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'mild hyponatremia'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '20'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'other (OTHER)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '3x a week'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '24 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '29 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User entered empty.	System	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User entered empty.	System	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:13
User entered empty.	System	22 Apr 2021 18:01:49

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, PRODUCT: ALL OTHER THERAPEUTIC PRODUCTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:58:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:58:01
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
Data point term sent to Coder	System	25 Apr 2021 14:55:14
Query 'CDM-Coding: The trade name NP BOLUS can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	25 Apr 2021 14:54:52
User opened query 'CDM-Coding: The trade name NP BOLUS can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	Coder Import (b) (4) (b) (4)	23 Apr 2021 11:54:45
Data point term sent to Coder	System	22 Apr 2021 18:12:52
User entered 'NP Bolus'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 09 Jun 2021 15:40:16

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'hydration'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '500'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'mL (mL)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'once (ONCE)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '26 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '0'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered '26 Nov 2020'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User signature succeeded.	John McGettigan (b) (4) (b) (4)	25 Apr 2021 17:52:29
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User entered empty.	System	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:40:16

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User entered empty.	System	22 Apr 2021 18:11:54

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 09 Jun 2021 15:40:16

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:17
User entered empty.	System	22 Apr 2021 18:11:54

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:40:16

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:30
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
Signature has been broken.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:29:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:29:30
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:48:56
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	10 Sep 2020 20:22:42

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered '27 Oct 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:30:15

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'Tooth Extraction'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:30:15

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'Other (OTHER)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:30:15

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:40:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'Dental'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:30:15

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered '27 Oct 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:31:15

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'Dental Bridge Procedure'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:31:15

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'Other (OTHER)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:31:15

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:40:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:11
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
User entered 'Dental work'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:31:15

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:23
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:08
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:31:32

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:23
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:08
User entered 'chest x-ray'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:31:32

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:23
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:08
User entered 'Diagnostic (DIAGNOSTIC)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:31:32

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:40:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:23
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:08
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:31:32

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:32
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:09
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:32:32

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:32
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:09
User entered 'Ekg'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:32:32

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:32
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:09
User entered 'Diagnostic (DIAGNOSTIC)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:32:32

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:40:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:32
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:09
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:32:32

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:42
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:10
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:32:58

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:42
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:10
User entered 'ultrasound retroperitoneal kidney'	Yvonne De Los Reyes	21 Apr 2021 18:32:58
	(b) (4)	

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:42
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:10
User entered 'Diagnostic (DIAGNOSTIC)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:32:58

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:40:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:42
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:10
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:32:58

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:55
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:11
User entered '10 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:33:12

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:55
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:11
User entered 'ECHO'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:33:12

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:11
User entered 'Diagnostic (DIAGNOSTIC)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:33:12

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:40:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:02:55
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:11
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:33:12

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:12
User entered '04 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:34:06

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:05
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:12
User entered 'CT abdomen w/o contrast'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:34:06

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:05
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:12
User entered 'Diagnostic (DIAGNOSTIC)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:34:06

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:40:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:05
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:12
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:34:06

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:45
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:14
User entered '09 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:35:11

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:14
User entered 'Chest x-ray'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:35:11

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:14
User entered 'Diagnostic (DIAGNOSTIC)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:35:11

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:40:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:45
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:14
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:35:11

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:04:03
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:15
User entered '03 Nov 2020'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:35:44

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:40:16

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:04:03
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:15
User entered 'nuclear medicine pulmonary ventilation and perfusion study'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:35:44

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:40:16

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:04:03
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:40:15
User entered 'Diagnostic (DIAGNOSTIC)'	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:35:44

US3192291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:40:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:04:03
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:19:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 01:40:15
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Apr 2021 18:35:44

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'USA-US097-2020-MRNA-1273-P301000004'	System	16 Nov 2020 22:11:20

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411296

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411297

Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'John'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411299

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'McGettigan'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '5390 E. Erickson Drive'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Tucson'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'AZ'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '85712'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		03 Feb 2021 14:47:07
User entered 'US'	System	16 Nov 2020 22:13:01

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:16

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 16:05:48
User entered '5'	System	07 Apr 2021 14:37:46
User entered '4'	System	26 Mar 2021 19:49:30
User entered '3'	System	03 Mar 2021 15:54:24
User entered '2'	System	03 Feb 2021 14:47:02
User entered '1'	System	16 Nov 2020 22:13:01

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'USA-US097-2020-MRNA-1273-P301000004'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411310

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411314

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'John'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'McGettigan'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '5390 E. Erickson Drive'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Tucson'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411318

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'AZ'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '85712'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		03 Feb 2021 14:47:07
User entered 'US'	System	16 Nov 2020 22:13:01

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 16:05:48
User entered '5'	System	07 Apr 2021 14:37:46
User entered '4'	System	26 Mar 2021 19:49:30
User entered '3'	System	03 Mar 2021 15:54:24
User entered '2'	System	03 Feb 2021 14:47:02
User entered '1'	System	16 Nov 2020 22:13:01

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:40:16

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
User entered '16/Nov/2020 22:12'	System	16 Nov 2020 22:13:01

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:40:16

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.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		03 Feb 2021 14:47:07
User entered '1'		16 Nov 2020 22:13:01

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'USA-US097-2020-MRNA-1273-P301000004'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411329

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411332

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'John'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'McGettigan'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '5390 E. Erickson Drive'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Tucson'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'AZ'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '85712'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411338

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		03 Feb 2021 14:47:07
User entered 'US'	System	16 Nov 2020 22:13:01

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:16

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 16:05:48
User entered '5'	System	07 Apr 2021 14:37:46
User entered '4'	System	26 Mar 2021 19:49:30
User entered '3'	System	03 Mar 2021 15:54:24
User entered '2'	System	03 Feb 2021 14:47:02
User entered '1'	System	16 Nov 2020 22:13:01

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 15:40:16
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
User entered '03/Feb/2021 09:47'	System	03 Feb 2021 14:47:02

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:40:16

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.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		03 Feb 2021 14:47:07
User entered '1'		03 Feb 2021 14:47:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

3947 of 4019

FDA-CBER-2022-1614-0411342

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'USA-US097-2020-MRNA-1273-P301000004'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411347

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:16

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'John'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'McGettigan'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411352

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '5390 E. Erickson Drive'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411353

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Tucson'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411354

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'AZ'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '85712'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		03 Feb 2021 14:47:07
User entered 'US'	System	16 Nov 2020 22:13:01

FDA-CBER-2022-1614-0411357

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:16

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 16:05:48
User entered '5'	System	07 Apr 2021 14:37:46
User entered '4'	System	26 Mar 2021 19:49:30
User entered '3'	System	03 Mar 2021 15:54:24
User entered '2'	System	03 Feb 2021 14:47:02
User entered '1'	System	16 Nov 2020 22:13:01

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:40:16

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:20:31
User entered '03/Mar/2021 10:54'	System	03 Mar 2021 15:54:24

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:40:16

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)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:37:20
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:20:31
User entered '1'		03 Mar 2021 15:54:24

Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'USA-US097-2020-MRNA-1273-P301000004'	System	16 Nov 2020 22:11:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:16

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411366

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'John'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'McGettigan'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '5390 E. Erickson Drive'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Tucson'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'AZ'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '85712'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411374

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		03 Feb 2021 14:47:07
User entered 'US'	System	16 Nov 2020 22:13:01

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 16:05:48
User entered '5'	System	07 Apr 2021 14:37:46
User entered '4'	System	26 Mar 2021 19:49:30
User entered '3'	System	03 Mar 2021 15:54:24
User entered '2'	System	03 Feb 2021 14:47:02
User entered '1'	System	16 Nov 2020 22:13:01

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:40:16

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:20:31
User entered '26/Mar/2021 15:49'	System	26 Mar 2021 19:49:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:37:20
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:20:31
User entered '1'		26 Mar 2021 19:49:30

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'USA-US097-2020-MRNA-1273-P301000004'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411383

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411385

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'John'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411387

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'McGettigan'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '5390 E. Erickson Drive'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411389

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Tucson'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'AZ'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411391

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '85712'	System	16 Nov 2020 22:11:20

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		03 Feb 2021 14:47:07
User entered 'US'	System	16 Nov 2020 22:13:01

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 16:05:48
User entered '5'	System	07 Apr 2021 14:37:46
User entered '4'	System	26 Mar 2021 19:49:30
User entered '3'	System	03 Mar 2021 15:54:24
User entered '2'	System	03 Feb 2021 14:47:02
User entered '1'	System	16 Nov 2020 22:13:01

FDA-CBER-2022-1614-0411394

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:41:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:36
User entered '07/Apr/2021 10:37'	System	07 Apr 2021 14:37:46

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:40:16

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)	23 Apr 2021 01:41:06
Reviewed for Safety.		07 Apr 2021 14:39:57
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:36
User entered '1'	(b) (4), (b) (6)	07 Apr 2021 14:37:46

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'USA-US097-2020-MRNA-1273-P301000004'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Yes (Y)'	System	16 Nov 2020 22:11:20

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411402

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411403

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'No (N)'	System	16 Nov 2020 22:11:20

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'John'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'McGettigan'	System	16 Nov 2020 22:11:20

FDA-CBER-2022-1614-0411406

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '5390 E. Erickson Drive'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'Tucson'	System	16 Nov 2020 22:11:20

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 15:40:16
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered 'AZ'	System	16 Nov 2020 22:11:20

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		16 Nov 2020 22:12:52
User entered '85712'	System	16 Nov 2020 22:11:20

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:49:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:06:46
Reviewed for Safety.		03 Feb 2021 14:47:07
User entered 'US'	System	16 Nov 2020 22:13:01

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:16

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 16:05:48
User entered '5'	System	07 Apr 2021 14:37:46
User entered '4'	System	26 Mar 2021 19:49:30
User entered '3'	System	03 Mar 2021 15:54:24
User entered '2'	System	03 Feb 2021 14:47:02
User entered '1'	System	16 Nov 2020 22:13:01

US3192291
Folder: SAE USA-US097-2020-MRNA-1273-P301000004
Form: Safety Report Form (6)
Generated On: 09 Jun 2021 15:40:16
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:41:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 19:44:34
User entered '08/Apr/2021 12:05'	System	08 Apr 2021 16:05:48

US3192291

Folder: SAE USA-US097-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:40:16

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)	23 Apr 2021 01:41:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 19:44:34
User entered '1'	(b) (4), (b) (6)	08 Apr 2021 16:05:48