

US3222189 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:04:27

All time stamps listed in this document are displayed in GMT

US3222189

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

[Participant ID](#)

US3222189

[mRNA-1273-P301 Completion Guidelines](#)

US3222189

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:41:57

Generated On: 09 Jun 2021 16:04:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3222189

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input checked="" type="radio"/>
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

US3222189

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Date of Informed Consent (<i>dd MMM yyyy</i>)	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3222189

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3222189

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Were any significant conditions reported?

Yes ☒

No ☐

US3222189

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Condition	CHRONIC ALCOHOLIC
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222189

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Condition	HERNIA - UMBILICAL
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3222189

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Condition	SHOULDER SURGERY FROM AN UNKNOWN CAUSE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3222189

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3222189

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Condition	GERD
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3222189

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:41:57

Generated On: 09 Jun 2021 16:04:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:21 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 11:21
Height (<i>xxx.x</i>)	170.2 cm
Weight (<i>xxx.x</i>)	66.7 kg
BMI (<i>xxx.x</i>)	23.02538 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3222189

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:41:57

Generated On: 09 Jun 2021 16:04:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3222189

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 21:41:57

Generated On: 09 Jun 2021 16:04:27

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☒ No ☐

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

US3222189

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 21:41:57

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3222189

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 105050

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Height	ND - Not Done
Weight	ND - Not Done

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 11:35
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	12:39 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 12:39
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3222189

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:41:57

Generated On: 09 Jun 2021 16:04:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3222189

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:41:57

Generated On: 09 Jun 2021 16:04:27

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 12:04 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 12:04

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

US3222189

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:41:57

Generated On: 09 Jun 2021 16:04:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 AUG 2020
Collection time (00:00-23:59)	11:55 (24 HR)
Collection date and time (derived)	17 AUG 2020 11:55

US3222189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:41:57

Generated On: 09 Jun 2021 16:04:27

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:58	17 AUG 2020 11:58
Nasopharyngeal Swab 2	No		

US3222189

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:57

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:35

PC Open Date & Time

17 AUG 2020 12:24

PC Close Date & Time

17 AUG 2020 14:54

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 17 AUG 2020 15:49

PC Close Date & Time 18 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 19:55

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 12:17

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

22 AUG 2020 06:45

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 08:13

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

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

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 12:35

PC Open Date & Time

17 AUG 2020 12:24

PC Close Date & Time

17 AUG 2020 14:54

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

17 AUG 2020 15:49

PC Close Date & Time

18 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

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

18 AUG 2020 19:55

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 4

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

20 AUG 2020 12:18

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 5

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

22 AUG 2020 06:45

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 7

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

24 AUG 2020 08:13

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

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 ☐

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 12:36
PC Open Date & Time	17 AUG 2020 12:24
PC Close Date & Time	17 AUG 2020 14:54

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

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 ☐

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

17 AUG 2020 15:49

PC Close Date & Time

18 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

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)

46 of 2393

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 19:56
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

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)

48 of 2393

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

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 ☒

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:18
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

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 ☒

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 06:46
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

54 of 2393

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

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 ☒

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 08:13
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3222189

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222189

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222189

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222189

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	11:06 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 11:06
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 12:15
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3222189

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3222189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 11:44 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 11:44

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

US3222189

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 SEP 2020
Collection time (00:00-23:59)	11:35 (24 HR)
Collection date and time (derived)	18 SEP 2020 11:35

US3222189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:30	18 SEP 2020 11:30
Nasopharyngeal Swab 2	No		

US3222189

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐
No ☒

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

PC Time Stamp

18 SEP 2020 12:15

PC Open Date & Time

18 SEP 2020 12:04

PC Close Date & Time

18 SEP 2020 14:34

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 18 SEP 2020 15:29

PC Close Date & Time 19 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

19 SEP 2020 17:07

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

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

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

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

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

18 SEP 2020 12:15

PC Open Date & Time

18 SEP 2020 12:04

PC Close Date & Time

18 SEP 2020 14:34

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

18 SEP 2020 15:29

PC Close Date & Time

19 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

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

19 SEP 2020 17:07

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

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 ☐

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 12:16
PC Open Date & Time	18 SEP 2020 12:04
PC Close Date & Time	18 SEP 2020 14:34

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

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 ☐

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 15:29

PC Close Date & Time

19 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

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 ☒

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 17:08
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

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)

94 of 2393

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

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 ☐

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

98 of 2393

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

100 of 2393

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

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 ☐

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3222189

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

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

LEFT SEVERAL MESSAGES + TO
EMERGENCY CONTACT
NUMBER WITH NO RETURN
CALL. I FOUND OUT ON
05/OCT/2020 THAT HE WAS IN
THE HOSPITAL. SAE

US3222189

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 OCT 2020

Please select one status for the follow-up contact
Contact Made ☐
Contact Not Made ☒

Comments
If Contact Not Made, please provide Comments
PATIENT REMAINS
HOSPITALIZED AND WILL
CALL ME WHEN HE IS
DISCHARGED.

US3222189

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 OCT 2020

Please select one status for the follow-up contact Contact Made ☐ Contact Not Made ☒

Comments 1 ATTEMPT MADE TO CONTACT
PATIENT ON 12 OCT 2020. 1
If Contact Not Made, please provide Comments ATTEMPT MADE TO CONTACT
PATIENT ON 13 OCT 2020. 1
ATTEMPT MADE TO CONTACT
PATIENT ON 14 OCT 2020.

US3222189

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222189

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

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.

US3222189

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 NOV 2020
Collection time (00:00-23:59)	15:30 (24 HR)
Collection date and time (derived)	2 NOV 2020 15:30

US3222189

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:58

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 92

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 18:33:27

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 15:25:27
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 23:44:39

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 110

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 07:26:52

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 14:00:37
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	23 DEC 2020 00:01
--	-------------------

Patient Cloud Close Date & Time	27 DEC 2020 23:59
---	-------------------

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 DEC 2020 08:21:42
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 16:01:20
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 JAN 2021 13:51:58
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	20 JAN 2021 15:18:11
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 10:16:31

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

03 FEB 2021 11:28:23

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 10:24:00
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 FEB 2021 09:21:02
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

24 FEB 2021 10:47:28

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

17 MAR 2021 12:28:02

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

24 MAR 2021 14:34:07

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

01 APR 2021 11:08:12

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

07 APR 2021 09:19:03

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

14 APR 2021 12:14:29

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	18 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	22 AUG 2021 23:59
---	-------------------

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	25 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	29 AUG 2021 23:59
---	-------------------

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2021 00:01
Patient Cloud Close Date & Time	05 SEP 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2021 00:01
Patient Cloud Close Date & Time	03 OCT 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	20 OCT 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	24 OCT 2021 23:59
---	-------------------

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	15 DEC 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	19 DEC 2021 23:59
---	-------------------

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature \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 ☐

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	26 JAN 2022 00:01
Patient Cloud Close Date & Time	30 JAN 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 ☐

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \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 ☐

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \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 ☐

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	09 OCT 2022 23:59
---	-------------------

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3222189

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:04:27

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
Yes	Yes	17 MAR 2021 12:28:49

US3222189

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222189

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222189

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222189

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

Please select one status for the follow-up contact Contact Made ☐ Contact Not Made ☒

Comments 1. LMOM @ 11:17
2. LMOM @ 14:21
If Contact Not Made, please provide Comments 3. LMOM @ 17:11

US3222189

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3222189

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:27

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.

US3222189

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3222189

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222189

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222189

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:04:27

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3222189

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:04:27

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222189

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	24 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3222189

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Date of updated informed consent (<i>dd MMM yyyy</i>)	24 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	24 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3222189

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 FEB 2021
Collection time (00:00-23:59)	11:10 (24 HR)
Collection date and time (derived)	24 FEB 2021 11:10

US3222189

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 FEB 2021
Collection time (00:00 - 23:59)	11:13
Collection Date and Time (derived)	24 FEB 2021 11:13

US3222189

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

AEID	USA-US104-2020-MRNA-1273-P30 1000007
Adverse event	ENCEPHALOPATHY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	02 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	03 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

331 of 2393

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

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 <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

I WAS LEFT A MESSAGE @ 15:02
TODAY FROM THE PATIENT
THAT HE HAS BEEN IN THE
HOSPITAL FOR THE LAST TWO
WEEKS FOR PRE-CANCEROUS
ULCER IN THE STOMACH AND
ESOPHAGUS. THIS IS ALL THE
INFORMATION I HAVE AND I
WILL UPDATE AS I GET MORE.

01/DEC/2020 I RECEIVED
MEDICAL RECORDS TODAY.
THE DATES OF ADMISSION
AND DISCHARGE WERE
INACURATELY PROPORTED BY
THE PATIENT TO ME. HE WAS
ADMITTED ON 02/OCT/2020 FOR
ENCEPHALOPATHY AND
VISUAL HALLUNINATIONS. HE
WAS BAKER ACTED AND
RECOMMEND HIM TO
INPATIENT PSYCHE WHEN
MEDICALLY CLEARED.

HE HAS A HISTORY OF
BIPOLAR DISORDER. OPON
ADMISSION, HIS CREATININE
WAS ELEVATED TO 2 WHERE
HE WAS STARTED ON IV
FLUIDS TO NORMAL LEVEL
1.26. HIS UA SHOWED UTI MILD
AND PATIENT DENIES DYSURIA
OR FREQUENCY. HE DOES NOT
HAVE LEUKOCYTOSIS. HE IS
AFEBRILE. NO INDICATIONS OF
ANTIBIOTICS. CT OF THE HEAD
WAS NEGATIVE FOR ACUTE

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

CHANGES. PATIENTS ALCOHOL
LEVEL WAS 114. PATIENT
STATES HE BINGES ON
OCCASION. NO WITHDRAWAL
SYMPTOMS. HE WAS
TRANSFERRED TO THE
PSYCHIATRIC WARD.
DISCHARGE DIAGNOSIS
1. ENCEPHALOPATHY
2. VISUAL HALLUCINATIONS
3. ACUTE KIDNEY INJURY
4. POLYSUBSTANCE ABUSE

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

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

AEID	USA-US104-2020-MRNA-1273-P30 1000007
Adverse event	CHRONIC ALCOHOLIC RELAPSE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

335 of 2393

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input checked="" type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

I WAS LEFT A MESSAGE @ 15:02
TODAY FROM THE PATIENT
THAT HE HAS BEEN IN THE
HOSPITAL FOR THE LAST TWO
WEEKS FOR PRE-CANCEROUS
ULCER IN THE STOMACH AND
ESOPHAGUS. THIS IS ALL THE
INFORMATION I HAVE AND I
WILL UPDATE AS I GET MORE.

01/DEC/2020 I RECEIVED
MEDICAL RECORDS TODAY.
THE DATES OF ADMISSION
AND DISCHARGE WERE
INACURATELY PROPORTED BY
THE PATIENT TO ME. HE WAS
ADMITTED ON 02/OCT/2020 FOR
ENCEPHALOPATHY AND
VISUAL HALLUNINATIONS. HE
WAS BAKER ACTED AND
RECOMMEND HIM TO
INPATIENT PSYCHE WHEN
MEDICALLY CLEARED.

HE HAS A HISTORY OF
BIPOLAR DISORDER. OPON
ADMISSION, HIS CREATININE
WAS ELEVATED TO 2 WHERE
HE WAS STARTED ON IV
FLUIDS TO NORMAL LEVEL
1.26. HIS UA SHOWED UTI MILD
AND PATIENT DENIES DYSURIA
OR FREQUENCY. HE DOES NOT
HAVE LEUKOCYTOSIS. HE IS
AFEBRILE. NO INDICATIONS OF
ANTIBIOTICS. CT OF THE HEAD
WAS NEGATIVE FOR ACUTE

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

CHANGES. PATIENTS ALCOHOL
LEVEL WAS 114. PATIENT
STATES HE BINGES ON
OCCASION. NO WITHDRAWAL
SYMPTOMS. HE WAS
TRANSFERRED TO THE
PSYCHIATRIC WARD.
DISCHARGE DIAGNOSIS
1. ENCEPHALOPATHY
2. VISUAL HALLUCINATIONS
3. ACUTE KIDNEY INJURY
4. POLYSUBSTANCE ABUSE

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

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

AEID	
Adverse event	WORSENING BIPOLAR DISORDER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	2 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

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 <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
WORSENING BIPOLAR DISORDER AND HAVING A BIPOLAR DISORDER WAS NOT DISCLOSED AT SCREENING.	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	
PRODUCTION RELEASE (v12.003 EAB) (1725)	
340 of 2393	

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

AEID

Adverse event

ACUTE KIDNEY INJURY

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 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)

3 OCT 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

PRODUCTION RELEASE (v12.003

341 of 2393

EAB) (1725)

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	ACUTE KIDNEY INJURY WAS A DIAGNOSIS AT HOSPITAL DISCHARGE.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

AEID

Adverse event

VISUAL HALLUCINATIONS

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 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)

3 OCT 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

PRODUCTION RELEASE (v12.003

343 of 2393

EAB) (1725)

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

AEID	
Adverse event	POLYSUBSTANCE ABUSE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	2 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 2393

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

AEID

Adverse event

URINARY TRACT INFECTION

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)

21 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)

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

PRODUCTION RELEASE (v12.003

347 of 2393

EAB) (1725)

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Apr 2021 13:55:00

Generated On: 09 Jun 2021 16:04:27

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

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

Yes ☒

No ☐

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

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

Name of Medication CALCIUM

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

350 of 2393

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration UNK

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)

352 of 2393

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

Name of Medication FOLIC ACID

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration UNK

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)

354 of 2393

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

Name of Medication MULTI-VITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration UNK

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)

356 of 2393

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

Name of Medication POTASSIUM

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration UNK

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)

358 of 2393

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

Name of Medication TURMERIC

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration UNK

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)

360 of 2393

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration UNK

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)

362 of 2393

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

Name of Medication IV FLUIDS

Prophylaxis Yes ☐
No ☒

Indication AE: ACUTE KIDNEY INJURY:
(CREATININE WAS ELEVATED
TO A 2 AND FLUIDS DROPPED
IT TO A 1.26.)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 2393

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		2 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

Name of Medication SULFAMETHOXAZOLE
TRIMETHOPRIM

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 800/160

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2393

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐
No ☒

Indication AE: URINARY TRACT
INFECTION

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

368 of 2393

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		7 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

Name of Medication UNKNOWN DERMAL FILLER

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN REASON FOR
DERMAL FILLER

Dose per administration UNKNOWN

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify DOSE IS UNKNOWN

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☒
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2393

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 13:55:01

Generated On: 09 Jun 2021 16:04:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN UNK 0000
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3222189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3222189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 OCT 2020	CT OF HEAD	Adverse Event	

US3222189

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:04:27

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

US3222189

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:04:27

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 ☐

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	08/OCT/2020 16:54
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

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/OCT/2020 09:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/NOV/2020 23:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/DEC/2020 10:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	08/DEC/2020 20:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/MAR/2021 13:56
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

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Apr 2021 13:55:02

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/MAR/2021 11:00
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

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LISA
Investigator's Last Name	HOLLOWAY
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LISA
Investigator's Last Name	HOLLOWAY
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/OCT/2020 21:41
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

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LISA
Investigator's Last Name	HOLLOWAY
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/OCT/2020 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

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LISA
Investigator's Last Name	HOLLOWAY
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/NOV/2020 22:35
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

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 21:41:55

Generated On: 09 Jun 2021 16:04:27

SAEID	USA-US104-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LISA
Investigator's Last Name	HOLLOWAY
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/DEC/2020 10:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3222189 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222189

Form: Participant Creation

Generated On: 09 Jun 2021 16:04:27

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'US3222189'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:20:31

US3222189

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:19

US3222189

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:20:32

US3222189

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:19

US3222189

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'SCRN'	System	17 Aug 2020 16:03:19

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:20:33

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '57'	(b) (4) douglas winter (b) (4) (b) (4)	02 Sep 2020 21:39:37

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'YEARS'	System	02 Sep 2020 21:39:37

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered '57'	System	17 Aug 2020 16:03:34

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Male (M)'	(b) (4) douglas winter (b) (4)	02 Sep 2020 21:39:37
	(b) (4)	

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Unknown (UNKNOWN)'	(b) (4) douglas winter (b) (4) (b) (4)	02 Sep 2020 21:39:37

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	02 Sep 2020 21:39:37

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	02 Sep 2020 21:39:37

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	02 Sep 2020 21:39:37

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	02 Sep 2020 21:39:37

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	02 Sep 2020 21:39:37

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	02 Sep 2020 21:39:37

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered empty.	(b) (4) douglas winter (b) (4)	02 Sep 2020 21:39:37
	(b) (4)	

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	02 Sep 2020 21:39:37

US3222189

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:27

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	02 Sep 2020 21:39:37

US3222189

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:27

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '17 Aug 2020'	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:34

US3222189

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:27

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'Aug 2020'	System	17 Aug 2020 16:03:34

US3222189

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:27

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered '2020'	System	17 Aug 2020 16:03:34

US3222189

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Amendment 2 (2)'	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:34

US3222189

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:27

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:34

US3222189

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:27

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered empty.	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:34

US3222189

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered empty.	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:34

US3222189

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'No (N)'	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:34

US3222189

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:20:32

US3222189

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'I'	System	17 Aug 2020 16:03:40

US3222189

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:04:27

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:40

US3222189

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:04:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	23 Oct 2020 22:46:21
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	18 Aug 2020 15:21:46
	(b) (4)	

US3222189

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as SOC: Psychiatric disorders, HLT: Substance related and addictive disorders, PT: Alcoholism, LLT: Chronic alcoholism - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 03:25:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 03:25:30
Data point term sent to Coder	System	23 Oct 2020 22:47:55
User entered 'CHRONIC ALCOHOLIC'	douglas winter (b) (4)	23 Oct 2020 22:47:17

US3222189

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UN UNK 2017'	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:47:17

US3222189

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:47:17

US3222189

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	23 Oct 2020 22:47:17

US3222189

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:47:17

US3222189

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:47:17

US3222189

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'Jan 2017'	System	23 Oct 2020 22:47:17

US3222189

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered '2017'	System	23 Oct 2020 22:47:17

US3222189

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	23 Oct 2020 22:47:17

US3222189

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	23 Oct 2020 22:47:17

US3222189

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 22:12:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 22:12:42
Data point term sent to Coder	System	10 Nov 2020 22:12:11
User closed query 'For coding purposes, please specify the location of the HERNIA. (e.g. Inguinal, Hiatus, Herniated disc, etc) and update the term with your response.' (Site from System).	System	10 Nov 2020 22:11:51
Query 'For coding purposes, please specify the location of the HERNIA. (e.g. Inguinal, Hiatus, Herniated disc, etc) and update the term with your response.' answered with 'UPDATED' (Site from System).	Albert Garcia (b) (4)	10 Nov 2020 22:11:51
Coding entries removed.	Albert Garcia (b) (4)	10 Nov 2020 22:11:42
User entered 'HERNIA - UMBILICAL' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 22:11:42
User opened query 'For coding purposes, please specify the location of the HERNIA. (e.g. Inguinal, Hiatus, Herniated disc, etc) and update the term with your response.' (Site from System).	Coder Import (b) (4)	29 Oct 2020 12:22:34
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Hernia, LLT: Hernia - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 22:49:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 22:49:42
Data point term sent to Coder	System	23 Oct 2020 22:48:55
User entered 'HERNIA'	douglas winter (b) (4)	23 Oct 2020 22:48:09

US3222189

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UN UNK 2012'	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:48:09

US3222189

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:48:09

US3222189

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	23 Oct 2020 22:48:09

US3222189

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UN UNK 2012'	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:48:09

US3222189

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:48:09

US3222189

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'Jan 2012'	System	23 Oct 2020 22:48:09

US3222189

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered '2012'	System	23 Oct 2020 22:48:09

US3222189

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'Jan 2012'	System	23 Oct 2020 22:48:09

US3222189

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered '2012'	System	23 Oct 2020 22:48:09

US3222189

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per CDM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:09:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder operation, LLT: Shoulder operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:15:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:15:28
Data point term sent to Coder	System	06 Apr 2021 20:16:58
Query 'Per CDM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'ADDED TO CONDITION' (Site from DM).	douglas winter (b) (4) (b) (4)	06 Apr 2021 20:16:23
Coding entries removed.	douglas winter (b) (4) (b) (4)	06 Apr 2021 20:16:11
User entered 'SHOULDER SURGERY FROM AN UNKNOWN CAUSE' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Apr 2021 20:16:11
User opened query 'Per CDM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:58:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder operation, LLT: Shoulder operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:50:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:50:34
Data point term sent to Coder	System	23 Oct 2020 22:49:55

US3222189

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:27

[Condition](#)

Audit	User	Time (GMT)
User entered 'SHOULDER SURGERY'	douglas winter (b) (4) (b) (4)	23 Oct 2020 22:49:38

US3222189

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UN UNK 2015'	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:49:38

US3222189

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:49:38

US3222189

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:49:38

US3222189

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4)	23 Oct 2020 22:49:38

US3222189

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	23 Oct 2020 22:49:38

US3222189

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'Jan 2015'	System	23 Oct 2020 22:49:38

US3222189

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered '2015'	System	23 Oct 2020 22:49:38

US3222189

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	23 Oct 2020 22:49:38

US3222189

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	23 Oct 2020 22:49:38

US3222189

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as SOC: Psychiatric disorders, HLG: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 18:17:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 18:17:59
Data point term sent to Coder	System	26 Mar 2021 18:17:19
User entered 'BIPOLAR DISORDER'	douglas winter (b) (4)	26 Mar 2021 18:17:05
	(b) (4)	

US3222189

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4)	26 Mar 2021 18:17:05

US3222189

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	26 Mar 2021 18:17:05

US3222189

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	26 Mar 2021 18:17:05

US3222189

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4)	26 Mar 2021 18:17:05

US3222189

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	26 Mar 2021 18:17:05

US3222189

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	26 Mar 2021 18:17:05

US3222189

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	26 Mar 2021 18:17:05

US3222189

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	26 Mar 2021 18:17:05

US3222189

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	26 Mar 2021 18:17:05

US3222189

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 18:19:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 18:19:27
Data point term sent to Coder	System	26 Mar 2021 18:18:20
User entered 'GERD'	douglas winter (b) (4)	26 Mar 2021 18:17:35
	(b) (4)	

US3222189

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4)	26 Mar 2021 18:17:35

US3222189

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	26 Mar 2021 18:17:35

US3222189

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	26 Mar 2021 18:17:35

US3222189

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	26 Mar 2021 18:17:35

US3222189

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	26 Mar 2021 18:17:35

US3222189

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	26 Mar 2021 18:17:35

US3222189

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	26 Mar 2021 18:17:35

US3222189

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	26 Mar 2021 18:17:35

US3222189

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered empty.	System	26 Mar 2021 18:17:35

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:22:56

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '17 Aug 2020'	Amber Vasquez (b) (4)	18 Aug 2020 15:22:56

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '11:21'	Amber Vasquez (b) (4)	18 Aug 2020 15:22:56

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered '17 Aug 2020 11:21'	System	18 Aug 2020 15:22:56

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '170.2' cm	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:22:56
DataPoint set to visible.	(b) (4) System	17 Aug 2020 16:03:40

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '66.7' kg	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:22:56
DataPoint set to visible.	(b) (4) System	17 Aug 2020 16:03:40

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
Amendment Manager: User entered '23.02538'	System	16 Sep 2020 23:59:46
User entered '23.0'	System	18 Aug 2020 15:22:56
DataPoint set to visible.	System	17 Aug 2020 16:03:40

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'kg/m2'	System	18 Aug 2020 15:22:56
DataPoint set to visible.	System	17 Aug 2020 16:03:40

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:59:32
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	24 Sep 2020 18:29:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	24 Sep 2020 18:29:48
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:35:03
User entered '36.8' C	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:22:56

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	24 Sep 2020 18:29:48
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	18 Aug 2020 15:22:56

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Amber Vasquez (b) (4)	18 Aug 2020 15:22:56

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 18:29:48
User entered '64'	Albert Garcia (b) (4)	18 Aug 2020 15:22:56
	(b) (4)	

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'bpm'	System	18 Aug 2020 15:22:56

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 18:29:48
User entered '17'	Albert Garcia (b) (4)	18 Aug 2020 15:22:56
	(b) (4)	

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'breaths/min'	System	18 Aug 2020 15:22:56

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 18:29:48
User entered '117'	Albert Garcia (b) (4)	18 Aug 2020 15:22:56
	(b) (4)	

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'mmHg'	System	18 Aug 2020 15:22:56

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 18:29:48
User entered '72'	Albert Garcia (b) (4)	18 Aug 2020 15:22:56
	(b) (4)	

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User entered 'mmHg'	System	18 Aug 2020 15:22:56

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59

US3222189

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59

US3222189

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:23:37

US3222189

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '17 Aug 2020'	Amber Vasquez (b) (4)	18 Aug 2020 15:23:37

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

[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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

[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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

[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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'I'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '0'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '0'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

[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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '0'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

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 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '0'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '0'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '0'	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:59
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Amber Vasquez (b) (4)	18 Aug 2020 15:24:27

US3222189

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:58

US3222189

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '17 Aug 2020'	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:58

US3222189

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[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 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	17 Aug 2020 16:03:58

US3222189

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'VISIT1'	System	17 Aug 2020 16:03:58

US3222189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:35:05

US3222189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:27

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:59:54
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:59:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 15:35:05
User entered '105050' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:35:05

US3222189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:27

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:35:05

US3222189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:27

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 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User closed query 'PER CDM: Please complete this section of the form. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 19:32:29
Query 'PER CDM: Please complete this section of the form. ' answered with 'COMPLETED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:53:32
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:53:25
User opened query 'PER CDM: Please complete this section of the form. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 18:01:30

US3222189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:27

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 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	Alicia Cevera (b) (4)	03 Sep 2020 13:53:25

US3222189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:53:25

US3222189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:27

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	Alicia Cevera (b) (4)	03 Sep 2020 13:53:25

US3222189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:53:25

US3222189

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:27

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	Albert Garcia (b) (4)	24 Sep 2020 18:30:08
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:41
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:38:12

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 19:32:06
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'REMOVED AS REQUESTED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:49
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:28:29
User entered '170.2' cm	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 19:32:08
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'REMOVED AS REQUESTED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:49
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:28:36
User entered '66.7' kg	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 19:32:06
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'REMOVED AS REQUESTED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:49
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:28:29
User entered '170.2' cm	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 19:32:08
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'REMOVED AS REQUESTED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:49
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:28:36
User entered '66.7' kg	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '17 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '11:35'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '17 Aug 2020 11:35'	System	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '36.8' C	Amber Vasquez (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '63'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'bpm'	System	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '18'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'breaths/min'	System	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '110'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'mmHg'	System	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '72'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'mmHg'	System	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 19:32:06
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'REMOVED AS REQUESTED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:49
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:28:29
User entered '170.2' cm	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 19:32:08
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'REMOVED AS REQUESTED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:47:49
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:28:36
User entered '66.7' kg	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '17 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:14:52
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, post dose time is 30 minutes. Please remove query.' (Site from System).	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:28:42
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 15:27:55
User entered '12:39'	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '17 Aug 2020 12:39'	System	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '36.7' C	Amber Vasquez (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '56'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'bpm'	System	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '18'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'breaths/min'	System	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '107'	Amber Vasquez (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'mmHg'	System	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '82'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'mmHg'	System	18 Aug 2020 15:27:55

US3222189

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	03 Sep 2020 13:52:06

US3222189

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '17 Aug 2020'	Alicia Cevera (b) (4)	03 Sep 2020 13:52:06

US3222189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	17 Aug 2020 16:19:38

US3222189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Jennifer Dittman (b) (4)	17 Aug 2020 16:19:38

US3222189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

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 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Jennifer Dittman (b) (4)	17 Aug 2020 16:19:38

US3222189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 16:19:38

US3222189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '17 Aug 2020'	Jennifer Dittman (b) (4)	17 Aug 2020 16:19:38

US3222189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '12:04'	Jennifer Dittman (b) (4)	17 Aug 2020 16:19:38

US3222189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '17 Aug 2020 12:04'	System	17 Aug 2020 16:19:38

US3222189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	17 Aug 2020 16:19:38

US3222189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'ONCE'	System	17 Aug 2020 16:19:38

US3222189

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 16:19:38

US3222189

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	18 Aug 2020 15:28:56

US3222189

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '17 Aug 2020'	Amber Vasquez (b) (4)	18 Aug 2020 15:28:56

US3222189

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '11:55'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:28:56

US3222189

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '17 Aug 2020 11:55'	System	18 Aug 2020 15:28:56

US3222189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:04:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '17 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:29:49

US3222189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:29:49

US3222189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:29:49

US3222189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '11:58'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:29:49

US3222189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '17 Aug 2020 11:58'	System	18 Aug 2020 15:29:49

US3222189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:29:49

US3222189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:29:49

US3222189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Amber Vasquez (b) (4)	18 Aug 2020 15:29:49

US3222189

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered empty.	System	18 Aug 2020 15:29:49

US3222189

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	18 Aug 2020 15:30:25

US3222189

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'I'	System	18 Aug 2020 15:30:25

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:35:03', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '0f1a850f-f7d5-4a8c-9007-38bff44e9760'	System	17 Aug 2020 16:35:29
User entered 'Yes (Y)'	System	17 Aug 2020 16:35:29

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:35:11', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '0f1a850f-f7d5-4a8c-9007-38bff44e9760'	System	17 Aug 2020 16:35:29
User entered '98.1'	System	17 Aug 2020 16:35:29

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:35:16', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '0f1a850f-f7d5-4a8c-9007-38bff44e9760'	System	17 Aug 2020 16:35:29
User entered 'No (N)'	System	17 Aug 2020 16:35:29

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:35:25', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '0f1a850f-f7d5-4a8c-9007-38bff44e9760'	System	17 Aug 2020 16:35:29
User entered '17 Aug 2020 12:35'	System	17 Aug 2020 16:35:29

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '17 Aug 2020 12:24'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '17 Aug 2020 14:54'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '17 Aug 2020 15:49'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 2'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:38:40', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '541a4627-a593-45d3-b622-90762a4ddeeb'	System	18 Aug 2020 23:55:19
User entered 'Yes (Y)'	System	18 Aug 2020 23:55:19

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:55:03', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '541a4627-a593-45d3-b622-90762a4ddeeb'	System	18 Aug 2020 23:55:19
User entered '97.9'	System	18 Aug 2020 23:55:19

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:55:09', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '541a4627-a593-45d3-b622-90762a4ddeeb'	System	18 Aug 2020 23:55:19
User entered 'No (N)'	System	18 Aug 2020 23:55:19

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:55:16', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '541a4627-a593-45d3-b622-90762a4ddeeb'	System	18 Aug 2020 23:55:19
User entered '18 Aug 2020 19:55'	System	18 Aug 2020 23:55:19

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 3'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 4'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:17:38', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'a42448dd-8758-4a6c-adac-2268bedcfc4'	System	20 Aug 2020 16:17:59
User entered 'Yes (Y)'	System	20 Aug 2020 16:17:59

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:17:46', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'a42448dd-8758-4a6c-adac-2268bedcfc4'	System	20 Aug 2020 16:17:59
User entered '98.1'	System	20 Aug 2020 16:17:59

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:17:51', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'a42448dd-8758-4a6c-adac-2268bedcfc4'	System	20 Aug 2020 16:17:59
User entered 'No (N)'	System	20 Aug 2020 16:17:59

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:17:56', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'a42448dd-8758-4a6c-adac-2268bedcfc4'	System	20 Aug 2020 16:17:59
User entered '20 Aug 2020 12:17'	System	20 Aug 2020 16:17:59

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 5'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:45:19', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7adbb25e-b132-45fa-a887-d632c239c92d'	System	22 Aug 2020 10:45:42
User entered 'Yes (Y)'	System	22 Aug 2020 10:45:42

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:45:29', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7adbb25e-b132-45fa-a887-d632c239c92d'	System	22 Aug 2020 10:45:42
User entered '97.4'	System	22 Aug 2020 10:45:42

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:45:35', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7adbb25e-b132-45fa-a887-d632c239c92d'	System	22 Aug 2020 10:45:42
User entered 'No (N)'	System	22 Aug 2020 10:45:42

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:45:39', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7adbb25e-b132-45fa-a887-d632c239c92d'	System	22 Aug 2020 10:45:42
User entered '22 Aug 2020 06:45'	System	22 Aug 2020 10:45:42

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 6'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 7'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:12:51', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '9104307c-02ca-4fd9-83d1-1eef204e8f6a'	System	24 Aug 2020 12:13:09
User entered 'Yes (Y)'	System	24 Aug 2020 12:13:09

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:12:57', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '9104307c-02ca-4fd9-83d1-1eef204e8f6a'	System	24 Aug 2020 12:13:09
User entered '95.5'	System	24 Aug 2020 12:13:09

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '9104307c-02ca-4fd9-83d1-1eef204e8f6a'	System	24 Aug 2020 12:13:09
User entered 'No (N)'	System	24 Aug 2020 12:13:09

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:05', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '9104307c-02ca-4fd9-83d1-1eef204e8f6a'	System	24 Aug 2020 12:13:09
User entered '24 Aug 2020 08:13'	System	24 Aug 2020 12:13:09

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:35:32', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '1347493d-bf08-4c99-9038-e6ea8c6f861f'	System	17 Aug 2020 16:35:58
User entered 'None (1)'	System	17 Aug 2020 16:35:58

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:35:36', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '1347493d-bf08-4c99-9038-e6ea8c6f861f'	System	17 Aug 2020 16:35:58
User entered 'No (N)'	System	17 Aug 2020 16:35:58

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:35:39', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '1347493d-bf08-4c99-9038-e6ea8c6f861f'	System	17 Aug 2020 16:35:58
User entered 'No (N)'	System	17 Aug 2020 16:35:58

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:35:49', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '1347493d-bf08-4c99-9038-e6ea8c6f861f'	System	17 Aug 2020 16:35:58
User entered 'None (1)'	System	17 Aug 2020 16:35:58

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:35:53', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '1347493d-bf08-4c99-9038-e6ea8c6f861f'	System	17 Aug 2020 16:35:58
User entered '17 Aug 2020 12:35'	System	17 Aug 2020 16:35:58

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '17 Aug 2020 12:24'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '17 Aug 2020 14:54'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '17 Aug 2020 15:49'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 2'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:55:33', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '5be20e25-bdb7-4891-b04f-64faa185f08e'	System	18 Aug 2020 23:55:50
User entered 'None (1)'	System	18 Aug 2020 23:55:50

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:55:36', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '5be20e25-bdb7-4891-b04f-64faa185f08e'	System	18 Aug 2020 23:55:50
User entered 'No (N)'	System	18 Aug 2020 23:55:50

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:55:39', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '5be20e25-bdb7-4891-b04f-64faa185f08e'	System	18 Aug 2020 23:55:50
User entered 'No (N)'	System	18 Aug 2020 23:55:50

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:55:44', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '5be20e25-bdb7-4891-b04f-64faa185f08e'	System	18 Aug 2020 23:55:50
User entered 'None (1)'	System	18 Aug 2020 23:55:50

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:55:48', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '5be20e25-bdb7-4891-b04f-64faa185f08e'	System	18 Aug 2020 23:55:50
User entered '18 Aug 2020 19:55'	System	18 Aug 2020 23:55:50

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 3'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 4'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:05', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '34dcdff2-e3b8-4831-8e04-eeb5dc7d48f6'	System	20 Aug 2020 16:18:26
User entered 'None (1)'	System	20 Aug 2020 16:18:26

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:09', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '34dcdff2-e3b8-4831-8e04-eeb5dc7d48f6'	System	20 Aug 2020 16:18:26
User entered 'No (N)'	System	20 Aug 2020 16:18:26

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:13', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '34dcdff2-e3b8-4831-8e04-eeb5dc7d48f6'	System	20 Aug 2020 16:18:26
User entered 'No (N)'	System	20 Aug 2020 16:18:26

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:17', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '34dcdff2-e3b8-4831-8e04-eeb5dc7d48f6'	System	20 Aug 2020 16:18:26
User entered 'None (1)'	System	20 Aug 2020 16:18:26

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:21', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '34dcdff2-e3b8-4831-8e04-eeb5dc7d48f6'	System	20 Aug 2020 16:18:26
User entered '20 Aug 2020 12:18'	System	20 Aug 2020 16:18:26

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 5'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:45:44', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7970eb40-4c74-4d8a-9ff8-abff2a765fae'	System	22 Aug 2020 10:46:00
User entered 'None (1)'	System	22 Aug 2020 10:46:00

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:45:47', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7970eb40-4c74-4d8a-9ff8-abff2a765fae'	System	22 Aug 2020 10:46:00
User entered 'No (N)'	System	22 Aug 2020 10:46:00

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:45:51', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7970eb40-4c74-4d8a-9ff8-abff2a765fae'	System	22 Aug 2020 10:46:00
User entered 'No (N)'	System	22 Aug 2020 10:46:00

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:45:53', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7970eb40-4c74-4d8a-9ff8-abff2a765fae'	System	22 Aug 2020 10:46:00
User entered 'None (1)'	System	22 Aug 2020 10:46:00

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:45:58', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7970eb40-4c74-4d8a-9ff8-abff2a765fae'	System	22 Aug 2020 10:46:00
User entered '22 Aug 2020 06:45'	System	22 Aug 2020 10:46:00

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 6'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 7'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:14', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '6adbd5ff-c115-4230-bfbd-10aa0a40cfe5'	System	24 Aug 2020 12:13:35
User entered 'None (1)'	System	24 Aug 2020 12:13:35

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:19', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '6adbd5ff-c115-4230-bfbd-10aa0a40cfe5'	System	24 Aug 2020 12:13:35
User entered 'No (N)'	System	24 Aug 2020 12:13:35

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:22', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '6adbd5ff-c115-4230-bfbd-10aa0a40cfe5'	System	24 Aug 2020 12:13:35
User entered 'No (N)'	System	24 Aug 2020 12:13:35

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:24', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '6adbd5ff-c115-4230-bfbd-10aa0a40cfe5'	System	24 Aug 2020 12:13:35
User entered 'None (1)'	System	24 Aug 2020 12:13:35

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:27', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '6adbd5ff-c115-4230-bfbd-10aa0a40cfe5'	System	24 Aug 2020 12:13:35
User entered '24 Aug 2020 08:13'	System	24 Aug 2020 12:13:35

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:36:02', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b108d1ab-9871-40aa-a28b-a96ffaeceb8b'	System	17 Aug 2020 16:36:39
User entered 'None (0)'	System	17 Aug 2020 16:36:39

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:36:05', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b108d1ab-9871-40aa-a28b-a96ffaeceb8b'	System	17 Aug 2020 16:36:39
User entered 'None (0)'	System	17 Aug 2020 16:36:39

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:36:11', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b108d1ab-9871-40aa-a28b-a96ffaeceb8b'	System	17 Aug 2020 16:36:39
User entered 'None (0)'	System	17 Aug 2020 16:36:39

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:36:14', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b108d1ab-9871-40aa-a28b-a96ffaeceb8b'	System	17 Aug 2020 16:36:39
User entered 'None (0)'	System	17 Aug 2020 16:36:39

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:36:17', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b108d1ab-9871-40aa-a28b-a96ffaeceb8b'	System	17 Aug 2020 16:36:39
User entered 'None (0)'	System	17 Aug 2020 16:36:39

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:36:23', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b108d1ab-9871-40aa-a28b-a96ffaeceb8b'	System	17 Aug 2020 16:36:39
User entered 'None (0)'	System	17 Aug 2020 16:36:39

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:36:32', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b108d1ab-9871-40aa-a28b-a96ffaeceb8b'	System	17 Aug 2020 16:36:39
User entered 'No (N)'	System	17 Aug 2020 16:36:39

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-17T12:36:37', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b108d1ab-9871-40aa-a28b-a96ffaeceb8b'	System	17 Aug 2020 16:36:39
User entered '17 Aug 2020 12:36'	System	17 Aug 2020 16:36:39

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '17 Aug 2020 12:24'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '17 Aug 2020 14:54'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '17 Aug 2020 15:49'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 2'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:56:02', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'bca71a15-9aa4-42cc-a31e-37056fe129b6'	System	18 Aug 2020 23:56:43
User entered 'None (0)'	System	18 Aug 2020 23:56:43

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:56:11', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'bca71a15-9aa4-42cc-a31e-37056fe129b6'	System	18 Aug 2020 23:56:43
User entered 'None (0)'	System	18 Aug 2020 23:56:43

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:56:14', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'bca71a15-9aa4-42cc-a31e-37056fe129b6'	System	18 Aug 2020 23:56:43
User entered 'None (0)'	System	18 Aug 2020 23:56:43

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:56:19', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'bca71a15-9aa4-42cc-a31e-37056fe129b6'	System	18 Aug 2020 23:56:43
User entered 'None (0)'	System	18 Aug 2020 23:56:43

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:56:27', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'bca71a15-9aa4-42cc-a31e-37056fe129b6'	System	18 Aug 2020 23:56:43
User entered 'None (0)'	System	18 Aug 2020 23:56:43

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:56:29', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'bca71a15-9aa4-42cc-a31e-37056fe129b6'	System	18 Aug 2020 23:56:43
User entered 'None (0)'	System	18 Aug 2020 23:56:43

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:56:37', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'bca71a15-9aa4-42cc-a31e-37056fe129b6'	System	18 Aug 2020 23:56:43
User entered 'No (N)'	System	18 Aug 2020 23:56:43

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-18T19:56:41', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'bca71a15-9aa4-42cc-a31e-37056fe129b6'	System	18 Aug 2020 23:56:43
User entered '18 Aug 2020 19:56'	System	18 Aug 2020 23:56:43

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 3'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 4'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:26', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '779aa1fe-8a9d-478d-851e-616fd9861a1e'	System	20 Aug 2020 16:18:53
User entered 'None (0)'	System	20 Aug 2020 16:18:53

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:30', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '779aa1fe-8a9d-478d-851e-616fd9861a1e'	System	20 Aug 2020 16:18:53
User entered 'None (0)'	System	20 Aug 2020 16:18:53

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:34', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '779aa1fe-8a9d-478d-851e-616fd9861a1e'	System	20 Aug 2020 16:18:53
User entered 'None (0)'	System	20 Aug 2020 16:18:53

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:37', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '779aa1fe-8a9d-478d-851e-616fd9861a1e'	System	20 Aug 2020 16:18:53
User entered 'None (0)'	System	20 Aug 2020 16:18:53

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:39', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '779aa1fe-8a9d-478d-851e-616fd9861a1e'	System	20 Aug 2020 16:18:53
User entered 'None (0)'	System	20 Aug 2020 16:18:53

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:42', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '779aa1fe-8a9d-478d-851e-616fd9861a1e'	System	20 Aug 2020 16:18:53
User entered 'None (0)'	System	20 Aug 2020 16:18:53

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:46', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '779aa1fe-8a9d-478d-851e-616fd9861a1e'	System	20 Aug 2020 16:18:53
User entered 'No (N)'	System	20 Aug 2020 16:18:53

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-20T12:18:49', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '779aa1fe-8a9d-478d-851e-616fd9861a1e'	System	20 Aug 2020 16:18:53
User entered '20 Aug 2020 12:18'	System	20 Aug 2020 16:18:53

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 5'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:46:02', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd4e9c81a-943a-46fe-98fa-4eabccc1376a'	System	22 Aug 2020 10:46:32
User entered 'None (0)'	System	22 Aug 2020 10:46:32

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:46:05', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd4e9c81a-943a-46fe-98fa-4eabccc1376a'	System	22 Aug 2020 10:46:32
User entered 'None (0)'	System	22 Aug 2020 10:46:32

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:46:09', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd4e9c81a-943a-46fe-98fa-4eabccc1376a'	System	22 Aug 2020 10:46:32
User entered 'None (0)'	System	22 Aug 2020 10:46:32

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:46:11', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd4e9c81a-943a-46fe-98fa-4eabccc1376a'	System	22 Aug 2020 10:46:32
User entered 'None (0)'	System	22 Aug 2020 10:46:32

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:46:14', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd4e9c81a-943a-46fe-98fa-4eabccc1376a'	System	22 Aug 2020 10:46:32
User entered 'None (0)'	System	22 Aug 2020 10:46:32

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:46:19', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd4e9c81a-943a-46fe-98fa-4eabccc1376a'	System	22 Aug 2020 10:46:32
User entered 'None (0)'	System	22 Aug 2020 10:46:32

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:46:24', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd4e9c81a-943a-46fe-98fa-4eabccc1376a'	System	22 Aug 2020 10:46:32
User entered 'No (N)'	System	22 Aug 2020 10:46:32

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-22T06:46:29', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd4e9c81a-943a-46fe-98fa-4eabccc1376a'	System	22 Aug 2020 10:46:32
User entered '22 Aug 2020 06:46'	System	22 Aug 2020 10:46:32

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 6'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 7'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:32', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '8ee21f7d-f596-47a0-bbcf-164d5b15fd89'	System	24 Aug 2020 12:13:55
User entered 'None (0)'	System	24 Aug 2020 12:13:55

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:35', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '8ee21f7d-f596-47a0-bbcf-164d5b15fd89'	System	24 Aug 2020 12:13:55
User entered 'None (0)'	System	24 Aug 2020 12:13:55

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:37', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '8ee21f7d-f596-47a0-bbcf-164d5b15fd89'	System	24 Aug 2020 12:13:55
User entered 'None (0)'	System	24 Aug 2020 12:13:55

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:40', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '8ee21f7d-f596-47a0-bbcf-164d5b15fd89'	System	24 Aug 2020 12:13:55
User entered 'None (0)'	System	24 Aug 2020 12:13:55

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:43', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '8ee21f7d-f596-47a0-bbcf-164d5b15fd89'	System	24 Aug 2020 12:13:55
User entered 'None (0)'	System	24 Aug 2020 12:13:55

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:45', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '8ee21f7d-f596-47a0-bbcf-164d5b15fd89'	System	24 Aug 2020 12:13:55
User entered 'None (0)'	System	24 Aug 2020 12:13:55

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:47', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '8ee21f7d-f596-47a0-bbcf-164d5b15fd89'	System	24 Aug 2020 12:13:55
User entered 'No (N)'	System	24 Aug 2020 12:13:55

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-08-24T08:13:51', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '8ee21f7d-f596-47a0-bbcf-164d5b15fd89'	System	24 Aug 2020 12:13:55
User entered '24 Aug 2020 08:13'	System	24 Aug 2020 12:13:55

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 16:19:38

US3222189

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:38:55

US3222189

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '24 Aug 2020'	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:38:55

US3222189

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:38:55

US3222189

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:38:55

US3222189

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	18 Sep 2020 15:55:40

US3222189

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'I'	System	18 Sep 2020 15:55:40

US3222189

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:39:17

US3222189

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '31 Aug 2020'	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:39:17

US3222189

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Contact Made (CONTACT MADE)'	douglas winter (b) (4)	22 Oct 2020 23:39:17

US3222189

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:39:17

US3222189

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	18 Sep 2020 15:55:48

US3222189

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'I'	System	18 Sep 2020 15:55:48

US3222189

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:40:04

US3222189

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '7 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:40:04

US3222189

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:40:04

US3222189

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:40:04

US3222189

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	18 Sep 2020 15:55:55

US3222189

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'I'	System	18 Sep 2020 15:55:55

US3222189

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	18 Sep 2020 15:56:06

US3222189

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '18 Sep 2020'	Jennifer Dittman (b) (4)	18 Sep 2020 15:56:06

US3222189

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[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 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	18 Sep 2020 15:56:06

US3222189

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'VISIT2'	System	18 Sep 2020 15:56:06

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '18 Sep 2020'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Sep 2020 18:35:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Sep 2020 18:35:22
User entered '11:06' reason for change: Data Entry Error	Albert Garcia (b) (4)	24 Sep 2020 18:35:22
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Sep 2020 18:35:03
User entered empty.	System	24 Sep 2020 18:35:03
	Albert Garcia (b) (4)	24 Sep 2020 18:35:03
	(b) (4)	

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '18 Sep 2020 11:06'	System	24 Sep 2020 18:35:22
User entered empty.	System	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '36.8' C	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '74'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'bpm'	System	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '16'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'breaths/min'	System	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '101'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'mmHg'	System	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '74'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'mmHg'	System	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '18 Sep 2020'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '12:15'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '18 Sep 2020 12:15'	System	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '36.8' C	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '69'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'bpm'	System	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '16'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'breaths/min'	System	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '115'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'mmHg'	System	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '71'	Albert Garcia (b) (4)	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'mmHg'	System	24 Sep 2020 18:35:03

US3222189

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	24 Sep 2020 18:33:34

US3222189

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '18 Sep 2020'	Albert Garcia (b) (4)	24 Sep 2020 18:33:34

US3222189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	18 Sep 2020 15:56:26

US3222189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Jennifer Dittman (b) (4)	18 Sep 2020 15:56:26

US3222189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

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 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Jennifer Dittman (b) (4)	18 Sep 2020 15:56:26

US3222189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 15:56:26

US3222189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '18 Sep 2020'	Jennifer Dittman (b) (4)	18 Sep 2020 15:56:26

US3222189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '11:44'	Jennifer Dittman (b) (4)	18 Sep 2020 15:56:26

US3222189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '18 Sep 2020 11:44'	System	18 Sep 2020 15:56:26

US3222189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	18 Sep 2020 15:56:26

US3222189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'ONCE'	System	18 Sep 2020 15:56:26

US3222189

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:27

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 15:56:26

US3222189

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Albert Garcia (b) (4)	24 Sep 2020 18:32:12

US3222189

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '18 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	24 Sep 2020 18:32:12

US3222189

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '11:35'	Albert Garcia (b) (4)	24 Sep 2020 18:32:12

US3222189

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '18 Sep 2020 11:35'	System	24 Sep 2020 18:32:12

US3222189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:04:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '18 Sep 2020'	Albert Garcia (b) (4)	24 Sep 2020 18:31:45

US3222189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	24 Sep 2020 18:31:45

US3222189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Albert Garcia (b) (4)	24 Sep 2020 18:31:45

US3222189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '11:30'	Albert Garcia (b) (4)	24 Sep 2020 18:31:45

US3222189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '18 Sep 2020 11:30'	System	24 Sep 2020 18:31:45

US3222189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	24 Sep 2020 18:31:45

US3222189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	Albert Garcia (b) (4)	24 Sep 2020 18:31:45

US3222189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Albert Garcia (b) (4)	24 Sep 2020 18:31:45

US3222189

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered empty.	System	24 Sep 2020 18:31:45

US3222189

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	18 Sep 2020 15:56:39

US3222189

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '1'	System	18 Sep 2020 15:56:39

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:14:43', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '95967d0a-c9ff-4acf-b275-a2a689ed6bde'	System	18 Sep 2020 16:15:18
User entered 'Yes (Y)'	System	18 Sep 2020 16:15:18

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:14:55', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '95967d0a-c9ff-4acf-b275-a2a689ed6bde'	System	18 Sep 2020 16:15:18
User entered '98.2'	System	18 Sep 2020 16:15:18

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:15:04', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '95967d0a-c9ff-4acf-b275-a2a689ed6bde'	System	18 Sep 2020 16:15:18
User entered 'No (N)'	System	18 Sep 2020 16:15:18

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:15:11', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '95967d0a-c9ff-4acf-b275-a2a689ed6bde'	System	18 Sep 2020 16:15:18
User entered '18 Sep 2020 12:15'	System	18 Sep 2020 16:15:18

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Sep 2020 12:04'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Sep 2020 14:34'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Sep 2020 15:29'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 2'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:07:24', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd0b55d63-83e7-488b-b536-b8ac1982506b'	System	19 Sep 2020 21:07:45
User entered 'Yes (Y)'	System	19 Sep 2020 21:07:45

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:07:31', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd0b55d63-83e7-488b-b536-b8ac1982506b'	System	19 Sep 2020 21:07:45
User entered '97.2'	System	19 Sep 2020 21:07:45

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:07:35', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd0b55d63-83e7-488b-b536-b8ac1982506b'	System	19 Sep 2020 21:07:45
User entered 'No (N)'	System	19 Sep 2020 21:07:45

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:07:39', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd0b55d63-83e7-488b-b536-b8ac1982506b'	System	19 Sep 2020 21:07:45
User entered '19 Sep 2020 17:07'	System	19 Sep 2020 21:07:45

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 3'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 4'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 5'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 6'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 7'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:15:18', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2ee6bb98-0f91-45da-a7cf-724c1b988350'	System	18 Sep 2020 16:15:46
User entered 'None (1)'	System	18 Sep 2020 16:15:46

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:15:29', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2ee6bb98-0f91-45da-a7cf-724c1b988350'	System	18 Sep 2020 16:15:46
User entered 'No (N)'	System	18 Sep 2020 16:15:46

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:15:32', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2ee6bb98-0f91-45da-a7cf-724c1b988350'	System	18 Sep 2020 16:15:46
User entered 'No (N)'	System	18 Sep 2020 16:15:46

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:15:37', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2ee6bb98-0f91-45da-a7cf-724c1b988350'	System	18 Sep 2020 16:15:46
User entered 'None (1)'	System	18 Sep 2020 16:15:46

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:15:40', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2ee6bb98-0f91-45da-a7cf-724c1b988350'	System	18 Sep 2020 16:15:46
User entered '18 Sep 2020 12:15'	System	18 Sep 2020 16:15:46

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Sep 2020 12:04'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Sep 2020 14:34'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Sep 2020 15:29'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 2'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:07:43', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '5232e89f-e104-422e-9d48-40e72534541f'	System	19 Sep 2020 21:08:01
User entered 'None (1)'	System	19 Sep 2020 21:08:01

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:07:47', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '5232e89f-e104-422e-9d48-40e72534541f'	System	19 Sep 2020 21:08:01
User entered 'No (N)'	System	19 Sep 2020 21:08:01

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:07:50', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '5232e89f-e104-422e-9d48-40e72534541f'	System	19 Sep 2020 21:08:01
User entered 'No (N)'	System	19 Sep 2020 21:08:01

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:07:54', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '5232e89f-e104-422e-9d48-40e72534541f'	System	19 Sep 2020 21:08:01
User entered 'None (1)'	System	19 Sep 2020 21:08:01

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:07:58', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '5232e89f-e104-422e-9d48-40e72534541f'	System	19 Sep 2020 21:08:01
User entered '19 Sep 2020 17:07'	System	19 Sep 2020 21:08:01

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 3'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 4'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 5'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 6'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 7'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:15:46', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '12d2e1eb-189a-472e-974a-897ae3fc3a78'	System	18 Sep 2020 16:16:17
User entered 'None (0)'	System	18 Sep 2020 16:16:17

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:15:51', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '12d2e1eb-189a-472e-974a-897ae3fc3a78'	System	18 Sep 2020 16:16:17
User entered 'None (0)'	System	18 Sep 2020 16:16:17

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:15:55', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '12d2e1eb-189a-472e-974a-897ae3fc3a78'	System	18 Sep 2020 16:16:17
User entered 'None (0)'	System	18 Sep 2020 16:16:17

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:15:59', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '12d2e1eb-189a-472e-974a-897ae3fc3a78'	System	18 Sep 2020 16:16:17
User entered 'None (0)'	System	18 Sep 2020 16:16:17

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:16:02', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '12d2e1eb-189a-472e-974a-897ae3fc3a78'	System	18 Sep 2020 16:16:17
User entered 'None (0)'	System	18 Sep 2020 16:16:17

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:16:05', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '12d2e1eb-189a-472e-974a-897ae3fc3a78'	System	18 Sep 2020 16:16:17
User entered 'None (0)'	System	18 Sep 2020 16:16:17

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:16:08', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '12d2e1eb-189a-472e-974a-897ae3fc3a78'	System	18 Sep 2020 16:16:17
User entered 'No (N)'	System	18 Sep 2020 16:16:17

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-18T12:16:12', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '12d2e1eb-189a-472e-974a-897ae3fc3a78'	System	18 Sep 2020 16:16:17
User entered '18 Sep 2020 12:16'	System	18 Sep 2020 16:16:17

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Sep 2020 12:04'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Sep 2020 14:34'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '18 Sep 2020 15:29'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 2'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:08:05', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2d4aaac7-93b3-4a8b-962d-ab6e99e87214'	System	19 Sep 2020 21:08:36
User entered 'None (0)'	System	19 Sep 2020 21:08:36

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:08:08', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2d4aaac7-93b3-4a8b-962d-ab6e99e87214'	System	19 Sep 2020 21:08:36
User entered 'None (0)'	System	19 Sep 2020 21:08:36

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:08:12', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2d4aaac7-93b3-4a8b-962d-ab6e99e87214'	System	19 Sep 2020 21:08:36
User entered 'None (0)'	System	19 Sep 2020 21:08:36

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:08:15', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2d4aaac7-93b3-4a8b-962d-ab6e99e87214'	System	19 Sep 2020 21:08:36
User entered 'None (0)'	System	19 Sep 2020 21:08:36

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:08:19', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2d4aaac7-93b3-4a8b-962d-ab6e99e87214'	System	19 Sep 2020 21:08:36
User entered 'None (0)'	System	19 Sep 2020 21:08:36

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:08:23', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2d4aaac7-93b3-4a8b-962d-ab6e99e87214'	System	19 Sep 2020 21:08:36
User entered 'None (0)'	System	19 Sep 2020 21:08:36

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:08:28', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2d4aaac7-93b3-4a8b-962d-ab6e99e87214'	System	19 Sep 2020 21:08:36
User entered 'No (N)'	System	19 Sep 2020 21:08:36

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a3ca01fba2e64ee)', Time: '2020-09-19T17:08:32', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2d4aaac7-93b3-4a8b-962d-ab6e99e87214'	System	19 Sep 2020 21:08:36
User entered '19 Sep 2020 17:08'	System	19 Sep 2020 21:08:36

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 3'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 4'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 5'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 6'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	18 Sep 2020 15:56:26
User entered 'Day 7'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

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)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 15:56:26

US3222189

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 15:56:26

US3222189

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	08 Oct 2020 15:13:32

US3222189

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '25 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	08 Oct 2020 15:13:32

US3222189

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) douglas winter (b) (4)	08 Oct 2020 15:13:32

US3222189

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'LEFT SEVERAL MESSAGES + TO EMERGENCY CONTACT NUMBER WITH NO RETURN CALL. I FOUND OUT ON 05/OCT/2020 THAT HE WAS IN THE HOSPITAL. SAE'	(b) (4) douglas winter (b) (4)	08 Oct 2020 15:13:32

US3222189

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	08 Oct 2020 15:13:39

US3222189

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'I'	System	08 Oct 2020 15:13:39

US3222189

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	08 Oct 2020 15:32:36

US3222189

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '5 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	08 Oct 2020 15:32:36

US3222189

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) douglas winter (b) (4) (b) (4)	08 Oct 2020 15:32:36

US3222189

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'PATIENT REMAINS HOSPITALIZED AND WILL CALL ME WHEN HE IS DISCHARGED.'	(b) (4) douglas winter (b) (4) (b) (4)	08 Oct 2020 15:32:36

US3222189

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	08 Oct 2020 15:32:44

US3222189

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'I'	System	08 Oct 2020 15:32:44

US3222189

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	23 Oct 2020 22:59:55
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Oct 2020 22:59:55
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	22 Oct 2020 23:41:58
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	22 Oct 2020 23:41:58

US3222189

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	23 Oct 2020 22:59:16
User entered empty; reason for change Data Entry Error	(b) (4)	
	douglas winter (b) (4)	22 Oct 2020 23:42:17
User entered '12 Oct 2020'	(b) (4)	
	douglas winter (b) (4)	22 Oct 2020 23:41:58
	(b) (4)	

US3222189

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) douglas winter (b) (4) (b) (4)	22 Oct 2020 23:41:58

US3222189

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '1 attempt made to contact patient on 12 Oct 2020. 1 attempt made to contact patient on 13 Oct 2020. 1 attempt made to contact patient on 14 Oct 2020.' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:48:29
User entered 'THE PATIENT REMAINS UNREACHABLE, NOT SURE WHY PER PROGNOSIS.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	22 Oct 2020 23:42:53
User entered 'THE PATIENT REMAINS UNREACHABLE.'	douglas winter (b) (4) (b) (4)	22 Oct 2020 23:41:58

US3222189

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	23 Oct 2020 23:00:07

US3222189

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'I'	System	23 Oct 2020 23:00:07

US3222189

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 20:59:14

US3222189

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 11:32:34
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'DATE IS CORRECT AS ENTERED' (Site from System).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 22:12:33
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Nov 2020 20:59:14
User entered '2 Nov 2020'	Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 20:59:14

US3222189

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[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 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Clinic (Clinic)'	Alicia Cevera (b) (4)	02 Nov 2020 20:59:14

US3222189

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'VISIT3'	System	02 Nov 2020 20:59:14

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Alicia Cevera (b) (4)	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered empty.	System	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered empty.	System	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered empty.	System	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered empty.	System	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	Alicia Cevera (b) (4)	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered empty.	System	02 Nov 2020 21:00:10

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37

US3222189

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37

US3222189

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 21:00:15

US3222189

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 21:00:15

US3222189

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 20:59:03

US3222189

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '2 Nov 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 20:59:03

US3222189

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered '15:30'	(b) (4) Alicia Cevera (b) (4) (b) (4)	02 Nov 2020 20:59:03

US3222189

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered '2 Nov 2020 15:30'	System	02 Nov 2020 20:59:03

US3222189

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:58
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	02 Nov 2020 21:00:24

US3222189

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'I'	System	02 Nov 2020 21:00:24

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 64'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33
Data entry locked.	System	17 Aug 2020 16:19:38
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33
Data entry locked.	System	17 Aug 2020 16:19:38
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 71'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33
Data entry locked.	System	17 Aug 2020 16:19:38
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33
Data entry locked.	System	17 Aug 2020 16:19:38
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 78'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33
Data entry locked.	System	17 Aug 2020 16:19:38
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:09:33
Data entry locked.	System	17 Aug 2020 16:19:38
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered 'Day 92'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2020-11-18T18:33:18', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '645b616b-69ba-4143-af72-fe14e674810e'	System	18 Nov 2020 23:33:35
User entered 'No (N)'	System	18 Nov 2020 23:33:35

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2020-11-18T18:33:20', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '645b616b-69ba-4143-af72-fe14e674810e'	System	18 Nov 2020 23:33:35
User entered 'No (N)'	System	18 Nov 2020 23:33:35

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2020-11-18T18:33:27', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '645b616b-69ba-4143-af72-fe14e674810e'	System	18 Nov 2020 23:33:35
User entered '18 Nov 2020 18:33:27'	System	18 Nov 2020 23:33:35

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 16:19:38

US3222189

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:38:20
Data entry locked.	System	17 Aug 2020 16:19:38
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 16:19:38

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2020-11-19T15:25:14', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '6f80c101-fa81-43a4-bfaa-7e65378a31a7'	System	19 Nov 2020 20:25:31
User entered 'No (N)'	System	19 Nov 2020 20:25:31

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2020-11-19T15:25:23', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '6f80c101-fa81-43a4-bfaa-7e65378a31a7'	System	19 Nov 2020 20:25:31
User entered 'No (N)'	System	19 Nov 2020 20:25:31

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2020-11-19T15:25:27', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '6f80c101-fa81-43a4-bfaa-7e65378a31a7' User entered '19 Nov 2020 15:25:27'	System	19 Nov 2020 20:25:31
	System	19 Nov 2020 20:25:31

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2020-11-25T23:44:23', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'c540f9d7-6671-4a27-863c-40a618abe769'	System	26 Nov 2020 04:44:44
User entered 'No (N)'	System	26 Nov 2020 04:44:44

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2020-11-25T23:44:35', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'c540f9d7-6671-4a27-863c-40a618abe769'	System	26 Nov 2020 04:44:44
User entered 'No (N)'	System	26 Nov 2020 04:44:44

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2020-11-25T23:44:39', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'c540f9d7-6671-4a27-863c-40a618abe769'	System	26 Nov 2020 04:44:44
User entered '25 Nov 2020 23:44:39'	System	26 Nov 2020 04:44:44

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2020-12-04T07:26:47', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2e9d3e32-c053-4e4d-86c0-bf4fdefd32ad'	System	04 Dec 2020 12:26:58
User entered 'No (N)'	System	04 Dec 2020 12:26:58

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2020-12-04T07:26:38', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2e9d3e32-c053-4e4d-86c0-bf4fdefd32ad'	System	04 Dec 2020 12:26:58
User entered 'No (N)'	System	04 Dec 2020 12:26:58

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2020-12-04T07:26:52', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2e9d3e32-c053-4e4d-86c0-bf4fdefd32ad'	System	04 Dec 2020 12:26:58
User entered '04 Dec 2020 07:26:52'	System	04 Dec 2020 12:26:58

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2020-12-16T14:00:29', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'ffbd868a-f9eb-4d10-b37c-9685601d1934'	System	16 Dec 2020 19:00:45
User entered 'No (N)'	System	16 Dec 2020 19:00:45

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2020-12-16T14:00:26', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'ffbd868a-f9eb-4d10-b37c-9685601d1934'	System	16 Dec 2020 19:00:45
User entered 'No (N)'	System	16 Dec 2020 19:00:45

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2020-12-16T14:00:37', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'ffbd868a-f9eb-4d10-b37c-9685601d1934'	System	16 Dec 2020 19:00:45
User entered '16 Dec 2020 14:00:37'	System	16 Dec 2020 19:00:45

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2020-12-30T08:20:47', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '9e328a19-9c16-4bae-9d3f-fe5559a59097'	System	30 Dec 2020 13:21:54
User entered 'Yes (Y)'	System	30 Dec 2020 13:21:54

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2020-12-30T08:20:54', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '9e328a19-9c16-4bae-9d3f-fe5559a59097'	System	30 Dec 2020 13:21:54
User entered 'Yes (Y)'	System	30 Dec 2020 13:21:54

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please 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 (e05c47d95e5ca90a)', Time: '2020-12-30T08:21:10', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '9e328a19-9c16-4bae-9d3f-fe5559a59097'	System	30 Dec 2020 13:21:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Dec 2020 13:21:54

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2020-12-30T08:21:16', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '9e328a19-9c16-4bae-9d3f-fe5559a59097'	System	30 Dec 2020 13:21:54
User entered 'No (N)'	System	30 Dec 2020 13:21:54

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2020-12-30T08:21:34', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '9e328a19-9c16-4bae-9d3f-fe5559a59097'	System	30 Dec 2020 13:21:54
User entered 'Yes (Y)'	System	30 Dec 2020 13:21:54

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please 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 (e05c47d95e5ca90a)', Time: '2020-12-30T08:21:36', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '9e328a19-9c16-4bae-9d3f-fe5559a59097'	System	30 Dec 2020 13:21:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Dec 2020 13:21:54

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2020-12-30T08:21:42', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '9e328a19-9c16-4bae-9d3f-fe5559a59097'	System	30 Dec 2020 13:21:54
User entered '30 Dec 2020 08:21:42'	System	30 Dec 2020 13:21:54

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-01-06T16:00:51', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b9644939-2002-4753-828c-8d6333c6100e'	System	06 Jan 2021 21:01:33
User entered 'No (N)'	System	06 Jan 2021 21:01:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-01-06T16:01:06', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b9644939-2002-4753-828c-8d6333c6100e'	System	06 Jan 2021 21:01:33
User entered 'Yes (Y)'	System	06 Jan 2021 21:01:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please 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 (e05c47d95e5ca90a)', Time: '2021-01-06T16:01:11', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b9644939-2002-4753-828c-8d6333c6100e'	System	06 Jan 2021 21:01:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 21:01:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-01-06T16:01:20', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b9644939-2002-4753-828c-8d6333c6100e'	System	06 Jan 2021 21:01:33
User entered '06 Jan 2021 16:01:20'	System	06 Jan 2021 21:01:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-01-14T13:51:40', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2950082e-73de-48b2-89b0-666d4ba75bc8'	System	14 Jan 2021 18:52:06
User entered 'Yes (Y)'	System	14 Jan 2021 18:52:06

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-01-14T13:51:19', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2950082e-73de-48b2-89b0-666d4ba75bc8'	System	14 Jan 2021 18:52:06
User entered 'No (N)'	System	14 Jan 2021 18:52:06

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-01-14T13:51:45', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2950082e-73de-48b2-89b0-666d4ba75bc8'	System	14 Jan 2021 18:52:06
User entered 'No (N)'	System	14 Jan 2021 18:52:06

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-01-14T13:51:52', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2950082e-73de-48b2-89b0-666d4ba75bc8'	System	14 Jan 2021 18:52:06
User entered 'No (N)'	System	14 Jan 2021 18:52:06

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-01-14T13:51:58', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2950082e-73de-48b2-89b0-666d4ba75bc8'	System	14 Jan 2021 18:52:06
User entered '14 Jan 2021 13:51:58'	System	14 Jan 2021 18:52:06

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-01-20T15:17:10', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'ca25d294-bd98-4381-90a4-f5dc6c530e89'	System	20 Jan 2021 20:18:29
User entered 'Yes (Y)'	System	20 Jan 2021 20:18:29

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-01-20T15:16:14', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'ca25d294-bd98-4381-90a4-f5dc6c530e89'	System	20 Jan 2021 20:18:29
User entered 'Yes (Y)'	System	20 Jan 2021 20:18:29

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Please 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 (e05c47d95e5ca90a)', Time: '2021-01-20T15:17:44', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'ca25d294-bd98-4381-90a4-f5dc6c530e89'	System	20 Jan 2021 20:18:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Jan 2021 20:18:29

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-01-20T15:17:16', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'ca25d294-bd98-4381-90a4-f5dc6c530e89'	System	20 Jan 2021 20:18:29
User entered 'No (N)'	System	20 Jan 2021 20:18:29

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-01-20T15:17:23', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'ca25d294-bd98-4381-90a4-f5dc6c530e89'	System	20 Jan 2021 20:18:29
User entered 'Yes (Y)'	System	20 Jan 2021 20:18:29

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Please 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 (e05c47d95e5ca90a)', Time: '2021-01-20T15:17:25', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'ca25d294-bd98-4381-90a4-f5dc6c530e89'	System	20 Jan 2021 20:18:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Jan 2021 20:18:29

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-01-20T15:18:11', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'ca25d294-bd98-4381-90a4-f5dc6c530e89'	System	20 Jan 2021 20:18:29
User entered '20 Jan 2021 15:18:11'	System	20 Jan 2021 20:18:29

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-01-27T10:16:04', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7ce48f0a-29dc-4776-bd73-e70468f4c69c'	System	27 Jan 2021 15:16:35
User entered 'No (N)'	System	27 Jan 2021 15:16:35

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-01-27T10:16:20', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7ce48f0a-29dc-4776-bd73-e70468f4c69c'	System	27 Jan 2021 15:16:35
User entered 'No (N)'	System	27 Jan 2021 15:16:35

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-01-27T10:16:31', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '7ce48f0a-29dc-4776-bd73-e70468f4c69c'	System	27 Jan 2021 15:16:35
User entered '27 Jan 2021 10:16:31'	System	27 Jan 2021 15:16:35

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-02-03T11:28:14', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2888dc75-91d1-45da-8b3e-35821f0abe9a'	System	03 Feb 2021 16:28:28
User entered 'No (N)'	System	03 Feb 2021 16:28:28

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-02-03T11:28:17', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2888dc75-91d1-45da-8b3e-35821f0abe9a'	System	03 Feb 2021 16:28:28
User entered 'No (N)'	System	03 Feb 2021 16:28:28

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-02-03T11:28:23', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '2888dc75-91d1-45da-8b3e-35821f0abe9a'	System	03 Feb 2021 16:28:28
User entered '03 Feb 2021 11:28:23'	System	03 Feb 2021 16:28:28

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-02-10T10:23:38', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '3ab83682-1ae9-4738-b9d6-eeb49889a1ee'	System	10 Feb 2021 15:24:04
User entered 'No (N)'	System	10 Feb 2021 15:24:04

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-02-10T10:23:33', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '3ab83682-1ae9-4738-b9d6-eeb49889a1ee'	System	10 Feb 2021 15:24:04
User entered 'No (N)'	System	10 Feb 2021 15:24:04

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-02-10T10:24:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '3ab83682-1ae9-4738-b9d6-eeb49889a1ee' User entered '10 Feb 2021 10:24:00'	System	10 Feb 2021 15:24:04
	System	10 Feb 2021 15:24:04

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-02-17T09:20:07', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '63fabbcd-fcc5-4d38-8af9-c15bd7f1ca31'	System	17 Feb 2021 14:21:09
User entered 'Yes (Y)'	System	17 Feb 2021 14:21:09

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-02-17T09:19:53', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '63fabbcd-fcc5-4d38-8af9-c15bd7f1ca31'	System	17 Feb 2021 14:21:09
User entered 'No (N)'	System	17 Feb 2021 14:21:09

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-02-17T09:20:17', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '63fabbcd-fcc5-4d38-8af9-c15bd7f1ca31'	System	17 Feb 2021 14:21:09
User entered 'No (N)'	System	17 Feb 2021 14:21:09

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-02-17T09:20:38', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '63fabbcd-fcc5-4d38-8af9-c15bd7f1ca31'	System	17 Feb 2021 14:21:09
User entered 'No (N)'	System	17 Feb 2021 14:21:09

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-02-17T09:21:02', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '63fabbcd-fcc5-4d38-8af9-c15bd7f1ca31'	System	17 Feb 2021 14:21:09
User entered '17 Feb 2021 09:21:02'	System	17 Feb 2021 14:21:09

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-02-24T10:47:13-05:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '4ed2db3e-0346-41eb-b8c1-8700741b96ed'	System	24 Feb 2021 15:47:32
User entered 'No (N)'	System	24 Feb 2021 15:47:32

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-02-24T10:47:19-05:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '4ed2db3e-0346-41eb-b8c1-8700741b96ed'	System	24 Feb 2021 15:47:32
User entered 'No (N)'	System	24 Feb 2021 15:47:32

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-02-24T10:47:28-05:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '4ed2db3e-0346-41eb-b8c1-8700741b96ed' User entered '24 Feb 2021 10:47:28'	System	24 Feb 2021 15:47:32

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-03-17T12:27:57-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '8c9bb385-c7cc-402c-a57f-2620538950fb'	System	17 Mar 2021 16:28:09
User entered 'No (N)'	System	17 Mar 2021 16:28:09

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-03-17T12:27:45-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '8c9bb385-c7cc-402c-a57f-2620538950fb'	System	17 Mar 2021 16:28:09
User entered 'No (N)'	System	17 Mar 2021 16:28:09

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-03-17T12:28:02-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '8c9bb385-c7cc-402c-a57f-2620538950fb' User entered '17 Mar 2021 12:28:02'	System	17 Mar 2021 16:28:09
	System	17 Mar 2021 16:28:09

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-03-24T14:33:55-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b5ca8fef-d596-49ba-93c4-2f7dd4c6674b'	System	24 Mar 2021 18:34:18
User entered 'No (N)'	System	24 Mar 2021 18:34:18

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-03-24T14:33:58-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b5ca8fef-d596-49ba-93c4-2f7dd4c6674b'	System	24 Mar 2021 18:34:18
User entered 'No (N)'	System	24 Mar 2021 18:34:18

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-03-24T14:34:07-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b5ca8fef-d596-49ba-93c4-2f7dd4c6674b' User entered '24 Mar 2021 14:34:07'	System	24 Mar 2021 18:34:18
	System	24 Mar 2021 18:34:18

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-04-01T11:08:03-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'dab151df-7529-407e-9efd-b8c37f95a0c3'	System	01 Apr 2021 15:08:18
User entered 'No (N)'	System	01 Apr 2021 15:08:18

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-04-01T11:08:08-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'dab151df-7529-407e-9efd-b8c37f95a0c3'	System	01 Apr 2021 15:08:18
User entered 'No (N)'	System	01 Apr 2021 15:08:18

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-04-01T11:08:12-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'dab151df-7529-407e-9efd-b8c37f95a0c3'	System	01 Apr 2021 15:08:18
User entered '01 Apr 2021 11:08:12'	System	01 Apr 2021 15:08:18

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-04-07T09:18:54-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b45cf73b-b7df-4d5a-8060-0eb170843c30'	System	07 Apr 2021 13:19:10
User entered 'No (N)'	System	07 Apr 2021 13:19:10

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-04-07T09:18:58-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b45cf73b-b7df-4d5a-8060-0eb170843c30'	System	07 Apr 2021 13:19:10
User entered 'No (N)'	System	07 Apr 2021 13:19:10

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-04-07T09:19:03-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'b45cf73b-b7df-4d5a-8060-0eb170843c30'	System	07 Apr 2021 13:19:10
User entered '07 Apr 2021 09:19:03'	System	07 Apr 2021 13:19:10

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[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 (e05c47d95e5ca90a)', Time: '2021-04-14T12:14:22-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '95848bbd-0bf3-4418-a5ea-e916420695ab' User entered 'No (N)'	System	14 Apr 2021 16:15:51
	System	14 Apr 2021 16:15:51

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

Have you been exposed to someone with 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 (e05c47d95e5ca90a)', Time: '2021-04-14T12:14:24-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '95848bbd-0bf3-4418-a5ea-e916420695ab' User entered 'No (N)'	System	14 Apr 2021 16:15:51

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-04-14T12:14:29-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: '95848bbd-0bf3-4418-a5ea-e916420695ab' User entered '14 Apr 2021 12:14:29'	System	14 Apr 2021 16:15:51
	System	14 Apr 2021 16:15:51

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:09:33

US3222189

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:09:33
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:09:33

US3222189

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:04:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:57:11
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'ADDED TO CONMED PAGE AND MED HISTORY PAGE' (Site from DM).	douglas winter (b) (4) (b) (4)	06 Apr 2021 20:24:21
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 10:15:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-03-17T12:28:45-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd9923e50-1fc0-402b-83d1-1e7791380d78'	System	17 Mar 2021 16:29:02
User entered 'Yes (Y)'	System	17 Mar 2021 16:29:02

US3222189

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:04:27

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-03-17T12:28:47-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd9923e50-1fc0-402b-83d1-1e7791380d78'	System	17 Mar 2021 16:29:02
User entered 'Yes (Y)'	System	17 Mar 2021 16:29:02

US3222189

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:04:27

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:25:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e05c47d95e5ca90a)', Time: '2021-03-17T12:28:49-04:00', User OID: 'PatientReportedOutcome (US3222189)', ODM File OID: 'd9923e50-1fc0-402b-83d1-1e7791380d78'	System	17 Mar 2021 16:29:02
User entered '17 Mar 2021 12:28:49'	System	17 Mar 2021 16:29:02

US3222189

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Dec 2020 16:12:35

US3222189

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
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) (4), (b) (6)	07 Dec 2020 18:17:49
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 'CONFIRM CORRECT' (Site from System).	Alicia Cevera (b) (4) (b) (4)	07 Dec 2020 16:14:03
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	07 Dec 2020 16:12:35
User entered '9 Nov 2020'	Alicia Cevera (b) (4) (b) (4)	07 Dec 2020 16:12:35

US3222189

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Dec 2020 16:12:35

US3222189

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Dec 2020 16:12:35

US3222189

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Dec 2020 16:15:44

US3222189

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:13:37
User entered 'I'	System	07 Dec 2020 16:15:44

US3222189

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 21:25:09

US3222189

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '14 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 21:25:09

US3222189

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 21:41:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) [REDACTED]	14 Dec 2020 21:25:09

US3222189

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 21:25:09

US3222189

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 21:26:00

US3222189

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User entered 'I'	System	14 Dec 2020 21:26:00

US3222189

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 16:00:14

US3222189

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '13 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 16:00:14

US3222189

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Jan 2021 16:00:14

US3222189

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 16:00:14

US3222189

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 16:00:19

US3222189

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User entered 'I'	System	18 Jan 2021 16:00:19

US3222189

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	26 Mar 2021 19:06:52

US3222189

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Mar 2021 19:07:07
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	26 Mar 2021 19:07:07
User entered '18 Feb 2021' reason for change: Data Entry Error	douglas winter (b) (4)	26 Mar 2021 19:07:07
	(b) (4)	
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Mar 2021 19:06:52
User entered '18 Mar 2021'	douglas winter (b) (4)	26 Mar 2021 19:06:52
	(b) (4)	

US3222189

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	douglas winter (b) (4)	26 Mar 2021 19:06:52
	(b) (4)	

US3222189

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '1. LMOM @ 11:17	douglas winter (b) (4)	26 Mar 2021 19:06:52
2. LMOM @ 14:21	(b) (4)	
3. LMOM @ 17:11'		

US3222189

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Mar 2021 11:27:58

US3222189

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:53
User entered 'I'	System	27 Mar 2021 11:27:58

US3222189

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:45:16

US3222189

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 12:45:16

US3222189

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:45:33

US3222189

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:45:33

US3222189

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:45:33

US3222189

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:45:33

US3222189

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:45:39

US3222189

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:27

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 12:45:39

US3222189

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	24 Feb 2021 22:08:08
	(b) (4)	

US3222189

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered '24 Feb 2021'	Diana Toney (b) (4)	24 Feb 2021 22:08:08
	(b) (4)	

US3222189

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	24 Feb 2021 22:08:08
	(b) (4)	

US3222189

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User entered 'UNBLND_DECIDE'	System	24 Feb 2021 22:08:08

US3222189

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:27

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered '24 Feb 2021'	Diana Toney (b) (4)	24 Feb 2021 22:08:43
	(b) (4)	

US3222189

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:27

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	25 Mar 2021 17:25:23
	Bruce Rankin (b) (4)	
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:18:25

US3222189

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:27

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	24 Feb 2021 22:08:43
	(b) (4)	

US3222189

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:27

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	25 Mar 2021 17:25:23
	Bruce Rankin (b) (4)	
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:18:25

US3222189

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:27

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered '24 Feb 2021'	Diana Toney (b) (4)	24 Feb 2021 22:08:43
	(b) (4)	

US3222189

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:27

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered 'Placebo (Placebo)'	Diana Toney (b) (4)	24 Feb 2021 22:08:43
	(b) (4)	

US3222189

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:27

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered 'Placebo (Placebo)'	Diana Toney (b) (4)	24 Feb 2021 22:08:43
	(b) (4)	

US3222189

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:27

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered 'Placebo (Placebo)'	Diana Toney (b) (4)	24 Feb 2021 22:08:43
	(b) (4)	

US3222189

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:27

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken.	douglas winter (b) (4)	26 Mar 2021 18:09:05
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	26 Mar 2021 18:09:05
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:39:03
User entered 'Yes (Y)'	Diana Toney (b) (4)	24 Feb 2021 22:08:43

US3222189

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:27

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User entered '1'	System	24 Feb 2021 22:08:43

US3222189

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:27

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User entered empty.	System	26 Mar 2021 18:09:05
User entered 'I'	System	24 Feb 2021 22:08:43

US3222189

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	24 Feb 2021 22:09:15
	(b) (4)	

US3222189

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered '24 Feb 2021'	Diana Toney (b) (4)	24 Feb 2021 22:09:15
	(b) (4)	

US3222189

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered '11:10'	Diana Toney (b) (4)	24 Feb 2021 22:09:15
	(b) (4)	

US3222189

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User entered '24 Feb 2021 11:10'	System	24 Feb 2021 22:09:15

US3222189

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	24 Feb 2021 22:09:37
	(b) (4)	

US3222189

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered '24 Feb 2021'	Diana Toney (b) (4)	24 Feb 2021 22:09:37
	(b) (4)	

US3222189

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:39:03
	Vicki Miller (b) (4)	
	(b) (4)	
User entered '11:13'	Diana Toney (b) (4)	24 Feb 2021 22:09:37
	(b) (4)	

US3222189

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:27

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:07:35
User entered '24 Feb 2021 11:13'	System	24 Feb 2021 22:09:37

US3222189

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:04:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:05:30
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	08 Oct 2020 15:32:58
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	18 Aug 2020 15:30:40

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:25:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:52:53
User entered		
'USA-US104-2020-mRNA-1273-P301000007'	System	08 Oct 2020 16:52:49
User entered 'New'	(b) (4), (b) (6)	08 Oct 2020 16:52:49

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Encephalopathies, HLT: Encephalopathies NEC, PT: Encephalopathy, LLT: Encephalopathy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 13:53:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 13:53:48
	(b) (4)	
Data point term sent to Coder	System	01 Dec 2020 13:52:39
DataPoint Un-verified.	douglas winter (b) (4)	01 Dec 2020 13:52:12
	(b) (4)	
Coding entries removed.	douglas winter (b) (4)	01 Dec 2020 13:52:12
	(b) (4)	
User entered 'ENCEPHALOPATHY' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:52:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:25:16
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: Tissue disorders NEC, HLT: Trophic disorders, PT: Precancerous condition, LLT: Precancerous condition - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 07:34:16
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 07:34:16
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 15:38:40
User entered 'PRE-CANCEROUS ULCER OF STOMACH AND ESOPHAGUS'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:25:46
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:25:38
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:28:07
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	10 Nov 2020 19:18:26
User entered 'No (N)' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	10 Nov 2020 19:18:19
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:58:35
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:25:51
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
DataPoint Un-verified.	douglas winter (b) (4)	01 Dec 2020 13:50:59
	(b) (4)	
User entered '02 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:50:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:25:53
User entered '21 Sep 2020'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:25:55
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Oct 2020 17:18:10
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	09 Oct 2020 17:18:10
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Oct 2020 15:38:04
User entered '00:00'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:18:10
User entered '21 Sep 2020 00:00'	System	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 13:51:20
DataPoint Un-verified.	douglas winter (b) (4)	01 Dec 2020 13:51:20
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:51:20
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 13:50:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:25:58
User entered 'Yes (Y)'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:50:51
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 15:39:51
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'UPDATED' (Site from System).	douglas winter (b) (4) (b) (4)	01 Dec 2020 13:52:33
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	01 Dec 2020 13:52:23
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 13:50:59
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	01 Dec 2020 13:50:59
User entered '03 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	01 Dec 2020 13:50:59
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:08:19
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:54:36
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'PENDING RECORDS' (Site from Safety).	douglas winter (b) (4) (b) (4)	15 Nov 2020 14:29:29
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:26:11

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:37:11
	douglas winter (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:26:06
User entered empty.	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	douglas winter (b) (4)	01 Dec 2020 15:18:51
reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	douglas winter (b) (4)	01 Dec 2020 13:52:48
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	douglas winter (b) (4)	01 Dec 2020 13:52:48
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:26:24
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:26:36
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:26:39
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:26:41
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:26:44
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 08:51:08
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'HOSPITAL ADMISSION DATE IS THERE' (Site from System).	douglas winter (b) (4)	08 Oct 2020 15:39:31
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	08 Oct 2020 15:38:04
User entered 'I'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
DataPoint Un-verified.	douglas winter (b) (4)	01 Dec 2020 13:50:59
	(b) (4)	
User entered '02 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:50:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:26:49
User entered '21 Sep 2020'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:39:41
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	01 Dec 2020 13:53:00
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	01 Dec 2020 13:50:59
User entered '03 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	01 Dec 2020 13:50:59
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:08:16
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:54:41
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'PENDING RECORDS' (Site from Safety).	douglas winter (b) (4) (b) (4)	15 Nov 2020 14:29:38
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:26:59
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:36:57
User entered empty.	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per source, ICU admission is marked Unknown. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:28:18
Query 'Per source, ICU admission is marked Unknown. Please verify and update accordingly.' answered with 'SOURCE HAS BEEN CORRECTED.' (Site from CRA).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 22:35:58
User opened query 'Per source, ICU admission is marked Unknown. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:27:53
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	09 Oct 2020 17:18:10
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		09 Oct 2020 17:18:10
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:18:10
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	08 Oct 2020 15:38:04
User entered 'Unknown (UNK)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:27:57
User entered empty.	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:27:59
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:01
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:02
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:07
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:13
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:47:57
Query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 22:49:21
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 22:36:21
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 22:36:21
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:25
User opened query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:36:45
User entered 'None (NONE)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	01 Dec 2020 14:24:51
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Dec 2020 14:23:42
User entered '0'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per CDM - RQ: Response noted "Updated". However no corresponding ConMed recorded that matched to this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:50:12
Query 'Per CDM - RQ: Response noted "Updated". However no corresponding ConMed recorded that matched to this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken' answered with 'PLEASE REVIEW MH LOG LINE #8.' (Site from DM).	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 17:09:34
User opened query 'Per CDM - RQ: Response noted "Updated". However no corresponding ConMed recorded that matched to this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 13:01:02
User closed query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 13:01:02
Query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. ' answered with 'UPDATED' (Site from DM).	douglas winter (b) (4) (b) (4)	01 Dec 2020 14:25:08
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	01 Dec 2020 14:24:51
User entered '0' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	01 Dec 2020 14:23:42
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 00:12:23
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).	(b) (4), (b) (6)	23 Nov 2020 00:12:23

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
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 'PENDING RECORDS' (Site from DM).	douglas winter (b) (4) (b) (4)	15 Nov 2020 14:29:55
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).	(b) (4), (b) (6)	01 Nov 2020 01:58:44
User entered '1'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:31:57
User entered '0'	douglas winter (b) (4)	08 Oct 2020 15:38:04
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:39:31
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'RESOLVED' (Site from Safety).	douglas winter (b) (4) (b) (4)	01 Dec 2020 14:25:24
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	01 Dec 2020 14:23:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	01 Dec 2020 14:23:42
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:08:13
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:54:47
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'PENDING RECORDS' (Site from Safety).	douglas winter (b) (4) (b) (4)	15 Nov 2020 14:30:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:31:59
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:37:50
User entered 'Unknown (UNKNOWN)'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:32:01
User entered empty.	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:40:38
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 15:40:25
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)	02 Dec 2020 15:40:17
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 15:39:22
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'I DID NOT SEE THAT COVID-19 SWAB WAS DONE AND I FOUND OUT TO LATE AFTER HIS DISCHARGE TO COMPLETE HIS NASAL SWAB IN THE HOSPITAL.' (Site from Safety).	douglas winter (b) (4) (b) (4)	01 Dec 2020 14:53:51
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 SENT TODAY' (Site from Safety).	douglas winter (b) (4) (b) (4)	01 Dec 2020 14:52:34

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[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 'CT DONE' (Site from Safety).	douglas winter (b) (4)	01 Dec 2020 14:25:54
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4)	01 Dec 2020 14:25:38

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User entered 'I WAS LEFT A MESSAGE @ 15:02 TODAY FROM THE PATIENT THAT HE HAS BEEN IN THE HOSPITAL FOR THE LAST TWO WEEKS FOR PRE-CANCEROUS ULCER IN THE STOMACH AND ESOPHAGUS. THIS IS ALL THE INFORMATION I HAVE AND I WILL UPDATE AS I GET MORE. 01/DEC/2020 I RECEIVED MEDICAL RECORDS TODAY. THE DATES OF ADMISSION AND DISCHARGE WERE INACURATELY PROPORTED BY THE PATIENT TO ME. HE WAS ADMITTED ON 02/OCT/2020 FOR ENCEPHALOPATHY AND VISUAL HALLUNINATIONS. HE WAS BAKER ACTED AND RECOMMEND HIM TO INPATIENT PSYCHE WHEN MEDICALLY CLEARED. HE HAS A HISTORY OF BIPOLAR DISORDER. OPON ADMISSION, HIS CREATININE WAS ELEVATED TO 2 WHERE HE WAS STARTED ON IV FLUIDS TO NORMAL LEVEL 1.26. HIS UA SHOWED UTI MILD AND PATIENT DENIES DYSURIA OR FREQUENCY. HE DOES NOT HAVE LEUKOCYTOSIS. HE IS AFEBRILE. NO INDICATIONS OF ANTIBIOTICS. CT OF THE HEAD WAS NEGATIVE FOR ACUTE CHANGES. PATIENTS ALCOHOL LEVEL WAS 114. PATIENT STATES HE BINGES ON OCCASION. NO WITHDRAWL SYMPTOMS. HE WAS TRANSFERRED TO THE PSYCHIATYTRIC WARD. DISCHARGE DIAGNOSIS 1. ENCEPHALPOPATHY 2. VISUAL HALLUCINATIONS 3. ACUTE KIDNEY INJURY 4. POLYSUBSTANCE ABUSE' reason for change: Data Entry Error DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	01 Dec 2020 14:22:55
	douglas winter (b) (4) (b) (4)	01 Dec 2020 14:22:11

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User entered 'I WAS LEFT A MESSAGE @ 15:02 TODAY FROM THE PATIENT THAT HE HAS BEEN IN THE HOSPITAL FOR THE LAST TWO WEEKS FOR PRE-CANCEROUS ULCER IN THE STOMACH AND ESOPHAGUS. THIS IS ALL THE INFORMATION I HAVE AND I WILL UPDATE AS I GET MORE. 01/DEC/2020 I RECEIVED MEDICAL RECORDS TODAY. THE DATES OF ADMISSION AND DISCHARGE WERE INACURATELY PROPORTED BY THE PATIENT TO ME. HE WAS ADMITTED ON 02/OCT/2020 FOR ENCEPHALOPATHY AND VISUAL HALLUNINATIONS. HE WAS BAKER ACTED AND RECOMMEND HIM TO INPATIENT PSYCHE WHEN MEDICALLY CLEARED. HE HAS A HISTORY OF BIPOLAR DISORDER. OPON ADMISSION, HIS CREATININE WAS ELEVATED TO 2 WHERE HE WAS STARTED ON IV FLUIDS TO NORMAL LEVEL 1.26. HIS UA SHOWED UTI MILD AND PATIENT DENIES DYSURIA OR FREQUENCY. HE DOES NOT HAVE LEUKOCYTOSIS. HE IS AFEBRILE. NO INDICATIONS OF ANTIBIOTICS. CT OF THE HEAD WAS NEGATIVE FOR ACUTE CHANGES. PATIENTS ALCOHOL LEVEL WAS 114. PATIENT STATES HE BINGES ON OCCASION. NO WITHDRAWL SYMPTOMS. HE WAS TRANSFERRED TO THE PSYCHIATYTRIC WARD. DISCHARGE DIAGNOSIS 1. ENCEPHALPOPATHY 2. HALLUCINATIONS 3. ACUTE KIDNEY INJURY 4. POLYSUBSTANCE ABUSE' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	01 Dec 2020 14:22:11
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:08:46

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:08:39
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:08:28
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:08:11
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:55:07
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:55:03
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)	16 Nov 2020 13:54:59
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:54:55

PRODUCTION RELEASE (v12.003
EAB) (1725)

1732 of 2393

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:54:51
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 'PENDING RECORDS' (Site from Safety).	douglas winter (b) (4) (b) (4)	15 Nov 2020 14:30:33
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'PENDING RECORDS' (Site from Safety).	douglas winter (b) (4) (b) (4)	15 Nov 2020 14:30:28
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 'PENDING RECORDS' (Site from Safety).	douglas winter (b) (4) (b) (4)	15 Nov 2020 14:30:23
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'PENDING RECORDS' (Site from Safety).	douglas winter (b) (4) (b) (4)	15 Nov 2020 14:30:19
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'PENDING RECORDS' (Site from Safety).	douglas winter (b) (4) (b) (4)	15 Nov 2020 14:30:14
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 23:48:04
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'SUBJECT'S MEDICAL HISTORY IS NOTED IN eCRF.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 22:51:39

PRODUCTION RELEASE (v12.003
EAB) (1725)

1733 of 2393

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:32:03
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).	(b) (4), (b) (6)	15 Oct 2020 13:39:31
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:38:34
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:38:25
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:38:18
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:37:41
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:37:32
User entered 'I WAS LEFT A MESSAGE @ 15:02 TODAY FROM THE PATIENT THAT HE HAS BEEN IN THE HOSPITAL FOR THE LAST TWO WEEKS FOR PRE-CANCEROUS ULCER IN THE STOMACH AND ESOPHAGUS. THIS IS ALL THE INFORMATION I HAVE AND I WILL UPDATE AS I GET MORE.'	douglas winter (b) (4) (b) (4)	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Oct 2020 15:38:04

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:18
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 01:06:13
User entered 'USA-US104-2020-mRNA-1273-P301000007' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 01:06:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:32:44
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:34
User entered 'USA-US104-2020-mRNA-1273-P301000013'	System	23 Oct 2020 21:41:21
User entered 'New' reason for change: New Information	(b) (4), (b) (6)	23 Oct 2020 21:41:21
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 12:22:17

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcoholism, LLT: Alcoholic relapse - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 19:38:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 19:38:56
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC ALCOHOLIC. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:58:04
Data point term sent to Coder	System	01 Dec 2020 17:02:56
Coding entries removed.	douglas winter (b) (4)	01 Dec 2020 17:02:24
User entered 'CHRONIC ALCOHOLIC RELAPSE' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 17:02:24
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC ALCOHOLIC. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'I ADDED WORSENING BIPOLAR DISORDER AS AN AE.' (Site from DM).	douglas winter (b) (4)	01 Dec 2020 16:18:48
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcoholism, LLT: Chronic alcoholism - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 13:51:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 13:51:47
Data point term sent to Coder	System	01 Dec 2020 13:50:37
Coding entries removed.	douglas winter (b) (4)	01 Dec 2020 13:49:43
User entered 'CHRONIC ALCOHOLIC' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:49:43

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Encephalopathies, HLT: Encephalopathies NEC, PT: Encephalopathy, LLT: Encephalopathy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 13:48:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 13:48:53
Data point term sent to Coder	System	01 Dec 2020 13:47:34
User entered 'ENCEPHALOPATHY' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:47:10
DataPoint Un-verified.	(b) (4)	
	douglas winter (b) (4)	01 Dec 2020 13:46:48
	(b) (4)	
Coding entries removed.	douglas winter (b) (4)	01 Dec 2020 13:46:48
	(b) (4)	
User entered 'ENCEPHALOPATHY' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:46:48
	(b) (4)	
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC ALCOHOLIC. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 00:12:34
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:32:46
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol abuse, LLT: Alcohol abuse - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 23:37:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 23:37:23
	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 23:36:44
User entered 'ALCOHOL ABUSE'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety). Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' answered with 'UPDATED' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:48:31
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Oct 2020 22:43:59
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety). User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4), (b) (6)	23 Oct 2020 12:22:10
	douglas winter (b) (4) (b) (4)	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '02 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:46:48
	(b) (4)	
User closed query 'PV Query: The EDC lists the start date as 22 Oct 2020, however the case narrative refers to a start of 10 Oct 2020. Please confirm and update the EDC as applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 22:34:19
Query 'PV Query: The EDC lists the start date as 22 Oct 2020, however the case narrative refers to a start of 10 Oct 2020. Please confirm and update the EDC as applicable.' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4)	10 Nov 2020 22:20:03
	(b) (4)	
User entered '10 Oct 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 22:19:58
	(b) (4)	
User opened query 'PV Query: The EDC lists the start date as 22 Oct 2020, however the case narrative refers to a start of 10 Oct 2020. Please confirm and update the EDC as applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:53:27
User entered '22 Oct 2020'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	22 Oct 2020 23:37:31
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	22 Oct 2020 23:37:31
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Oct 2020 23:35:51
User entered '16:40'	douglas winter (b) (4)	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 23:37:31
User entered '22 Oct 2020 16:40'	System	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:44:53
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 16:41:55
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:41:55
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 16:41:37
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:37:49
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:46:48
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for event: chronic alcoholic relapse' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:55:21
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for event: chronic alcoholic relapse' answered with 'This is still ongoing' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:57:36
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for event: chronic alcoholic relapse' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 16:25:10
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for event: chronic alcoholic relapse' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:43:31
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for event: chronic alcoholic relapse' answered with 'THIS AE IS NOT RESOLVED AND MAY BE A LONG TERM AE WITH NO RESOLUTION. ' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 17:10:34
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for event: chronic alcoholic relapse' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 21:09:11
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 15:42:37

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 16:44:53
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	01 Dec 2020 16:44:53
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:44:53
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4)	01 Dec 2020 16:43:16
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 16:41:37
User entered '30 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:41:37
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	01 Dec 2020 16:37:49
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 16:34:27
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	01 Dec 2020 16:34:27
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	01 Dec 2020 16:34:27
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:34:27
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 13:46:48
User entered '03 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:46:48

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	30 Oct 2020 17:53:02
	douglas winter (b) (4)	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query '(AE #2) PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for event: chronic alcoholic relapse' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:56:08
Query '(AE #2) PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for event: chronic alcoholic relapse' answered with 'STILL ONGOING' (Site from Safety).	douglas winter (b) (4) (b) (4)	26 Mar 2021 18:23:40
User opened query '(AE #2) PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for event: chronic alcoholic relapse' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 13:54:03
User entered empty.	douglas winter (b) (4) (b) (4)	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	douglas winter (b) (4)	01 Dec 2020 13:46:48
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:58:32
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'I DONT HAVE THAT INFORMATION YET, I JUST KNOW HE IS IN REHAB BECAUSE HE CALLED THE CLINIC TODAY.' (Site from System).	douglas winter (b) (4) (b) (4)	22 Oct 2020 23:37:18
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	22 Oct 2020 23:35:51
User entered 'I'	douglas winter (b) (4) (b) (4)	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '10 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:41:01
	(b) (4)	
User entered '02 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:46:48
	(b) (4)	
User entered '10 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:43:42
	(b) (4)	
User entered empty.	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 15:42:29
User entered '30 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:41:01
	(b) (4)	
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'UPDATED DATE' (Site from Safety).	douglas winter (b) (4)	01 Dec 2020 16:35:42
	(b) (4)	
User entered '03 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 13:46:48
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:52:39
User entered empty.	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:43:42
	(b) (4)	
User entered empty.	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:43:42
	(b) (4)	
User entered '0'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'PV Query: As the last dose of mRNA-1273 was given on 18 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:42:57
Query 'PV Query: As the last dose of mRNA-1273 was given on 18 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable.' answered with 'UPDATED TO NOT APPLICABLE' (Site from Safety).	douglas winter (b) (4) (b) (4)	01 Dec 2020 16:36:07
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	01 Dec 2020 16:34:56
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 18 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:48:01
User closed query 'PV Query: As the last dose of mRNA-1273 was given on 18 Sep 2020, please update the action taken with mRNA-1273 from dose delayed to not applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 22:34:27
Query 'PV Query: As the last dose of mRNA-1273 was given on 18 Sep 2020, please update the action taken with mRNA-1273 from dose delayed to not applicable.' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 22:23:14
User entered 'None (NONE)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 22:16:57
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 18 Sep 2020, please update the action taken with mRNA-1273 from dose delayed to not applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:52:28
User entered 'Dose Delayed (DOSE DELAYED)'	douglas winter (b) (4) (b) (4)	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0' reason for change: Data Entry Error	douglas winter (b) (4)	26 Mar 2021 18:27:47
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Mar 2021 18:26:18
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	26 Mar 2021 18:26:18
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Mar 2021 14:58:06
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:46:17
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'UPDATED' (Site from DM).	douglas winter (b) (4)	01 Dec 2020 16:46:12
	(b) (4)	
User entered '0' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:45:40
	(b) (4)	
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 00:12:58
User entered '1'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per CDM: Response noted. However the updatation is obvious. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 09:30:59
Query 'Per CDM: Response noted. However the updatation is obvious. Please review and update accordingly. Else clarify.' answered with 'BAKER ACTED AND ADMITTED TO A PSYCHE CENTER' (Site from DM).	douglas winter (b) (4) (b) (4)	26 Mar 2021 18:28:10
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	26 Mar 2021 18:27:47
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Therapeutic Procedure that match this AE during this time frame. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 07:47:13
User opened query 'Per CDM: Response noted. However the updatation is obvious. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 07:47:11
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Therapeutic Procedure that match this AE during this time frame. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' answered with 'none recorded' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:58:35
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 14:58:06
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Therapeutic Procedure that match this AE during this time frame. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 06:20:38
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	01 Dec 2020 16:45:40
User entered '0'	douglas winter (b) (4) (b) (4)	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query ' PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved for event chronic alcoholic relapse' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:56:13
Query ' PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved for event chronic alcoholic relapse' answered with 'CONTINUES TO RELAPSE, NOT SURE IF THIS WILL BE RESOLVED.' (Site from Safety).	douglas winter (b) (4) (b) (4)	26 Mar 2021 18:29:52
User opened query ' PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved for event chronic alcoholic relapse' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 16:25:59
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved for event chronic alcoholic relapse' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:43:37
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved for event chronic alcoholic relapse' answered with 'THIS IS NOT EXPECTED TO RESOLVE SHORT TERM. ' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 17:13:38
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved for event chronic alcoholic relapse' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 21:09:22

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:44:53
User entered 'Unknown (UNKNOWN)'	douglas winter (b) (4)	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	22 Oct 2020 23:35:51
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per DM CLR: Narrative indicates that the subject had a History of Bipolar Disorder. However, there is no corresponding MH record that match the information. Please review and update to record the corresponding MH as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 12:43:24
Query 'Per DM CLR: Narrative indicates that the subject had a History of Bipolar Disorder. However, there is no corresponding MH record that match the information. Please review and update to record the corresponding MH as appropriate. Otherwise, clarify.' answered with 'UPDATED MH' (Site from DM).	douglas winter (b) (4) (b) (4)	26 Mar 2021 18:25:01
User opened query 'Per DM CLR: Narrative indicates that the subject had a History of Bipolar Disorder. However, there is no corresponding MH record that match the information. Please review and update to record the corresponding MH as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 06:21:26
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)	02 Dec 2020 15:42:47
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 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	01 Dec 2020 16:47:48

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User entered 'I WAS LEFT A MESSAGE @ 15:02 TODAY FROM THE PATIENT THAT HE HAS BEEN IN THE HOSPITAL FOR THE LAST TWO WEEKS FOR PRE-CANCEROUS ULCER IN THE STOMACH AND ESOPHAGUS. THIS IS ALL THE INFORMATION I HAVE AND I WILL UPDATE AS I GET MORE. 01/DEC/2020 I RECEIVED MEDICAL RECORDS TODAY. THE DATES OF ADMISSION AND DISCHARGE WERE INACURATELY PROPORTED BY THE PATIENT TO ME. HE WAS ADMITTED ON 02/OCT/2020 FOR ENCEPHALOPATHY AND VISUAL HALLUNINATIONS. HE WAS BAKER ACTED AND RECOMMEND HIM TO INPATIENT PSYCHE WHEN MEDICALLY CLEARED. HE HAS A HISTORY OF BIPOLAR DISORDER. OPON ADMISSION, HIS CREATININE WAS ELEVATED TO 2 WHERE HE WAS STARTED ON IV FLUIDS TO NORMAL LEVEL 1.26. HIS UA SHOWED UTI MILD AND PATIENT DENIES DYSURIA OR FREQUENCY. HE DOES NOT HAVE LEUKOCYTOSIS. HE IS AFEBRILE. NO INDICATIONS OF ANTIBIOTICS. CT OF THE HEAD WAS NEGATIVE FOR ACUTE CHANGES. PATIENTS ALCOHOL LEVEL WAS 114. PATIENT STATES HE BINGES ON OCCASION. NO WITHDRAWL SYMPTOMS. HE WAS TRANSFERRED TO THE PSYCHIATYTRIC WARD. DISCHARGE DIAGNOSIS 1. ENCEPHALPOPATHY 2. VISUAL HALLUCINATIONS 3. ACUTE KIDNEY INJURY 4. POLYSUBSTANCE ABUSE' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	01 Dec 2020 16:47:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:47:36

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
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.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:47:34
User closed query 'PV Query: Please provide further details of COVID-19 testing and add it as an AE/SAE if it meets reporting criteria.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 22:34:41
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 22:34:35
Query 'PV Query: Please provide further details of COVID-19 testing and add it as an AE/SAE if it meets reporting criteria.' answered with 'IT APPEARS THAT THE COVID-19 POSITIVE STAED BY THE PATIENT WAS A MISINFORMATION.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 22:25:33
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'THERE ARE NO NEW CONMEDS THAT WE ARE AWARE OF.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 22:24:30
User opened query 'PV Query: Please provide further details of COVID-19 testing and add it as an AE/SAE if it meets reporting criteria.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:54:57
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:54:15

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:53:45
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:53:37
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:52:50
User entered 'FOUND OUT ON 22/OCT/2020 AT 16:40 HRS BY OUR FRONT DESK STAFF THAT THE PATIENT CALLED IN WITH HIS COUNSELOR SAYING HES IN A REHAB FACILITY AND NOT SURE WHEN HE WILL BE GETTING OUT BUT WILL CALL BACK. HE CALLED BACK 23/OCT/2020 CONFIRMING START DATE 10/OCT/2020, NO MEDICATIONS PRESCRIBED TO HIM, NO MEDICAL DIAGNOSTIC PROCEDURES, STATES HE IS POSITIVE COVID-19 ON 22/OCT/2020 BUT ASYMPTOMATIC, DIAGNOSED CHRONIC ALCHOLISM SINCE 2017, UNKNOWN DISCHARGE DATE.' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:45:49

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User entered 'FOUND OUT ON 22/OCT/2020 AT 16:40 HRS BY OUR FRONT DESK STAFF THAT THE PATIENT CALLED IN WITH HIS COUNSELOR SAYING HES IN A REHAB FACILITY AND NOT SURE WHEN HE WILL BE GETTING OUT BUT WILL CALL BACK. HE CALLED BACK 23/OCT/2020 CONFIRMING START DATE 10/OCT/2020, NO MEDICATIONS PRESCRIBED TO HIM, NO PROCEDURES, NO DIAGNOSTIC PROCEDURES, DIAGNOSED CHRONIC ALCHOLISM SINCE 2017, UNKNOWN DISCHARGE DATE.' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:43:42
User entered 'FOUND OUT ON 22/OCT/2020 AT 16:40 HRS THAT THE PATIENT CALLED IN WITH HIS COUNSELOR SAYING HES IN A REHAB FACILITY AND NOT SURE WHEN HE WILL BE GETTING OUT.'	douglas winter (b) (4)	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 23:35:51

US3222189

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 22:43:42

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per DM CLR: Please review this worsening AE and please note, there is no corresponding MH or prior AE record to support this worsening condition. Please update to record the baseline condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 12:43:46
Query 'Per DM CLR: Please review this worsening AE and please note, there is no corresponding MH or prior AE record to support this worsening condition. Please update to record the baseline condition as appropriate. Otherwise, clarify.' answered with 'UPDATED MH' (Site from DM).	douglas winter (b) (4) (b) (4)	26 Mar 2021 18:20:41
User opened query 'Per DM CLR: Please review this worsening AE and please note, there is no corresponding MH or prior AE record to support this worsening condition. Please update to record the baseline condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 06:26:31
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 08:19:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 08:19:09
Data point term sent to Coder	System	01 Dec 2020 16:09:41
User entered 'WORSENING BIPOLAR DISORDER'	douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '2 Oct 2020'	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 12:43:56
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'STILL ONGOING' (Site from DM).	douglas winter (b) (4) (b) (4)	26 Mar 2021 18:21:42
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 06:25:38
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	01 Dec 2020 16:09:23
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:09:23
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	01 Dec 2020 16:09:13
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	01 Dec 2020 16:09:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'WORSENING BIPOLAR DISORDER AND HAVING A BIPOLAR DISORDER WAS NOT DISCLOSED AT SCREENING.'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Dec 2020 16:09:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
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 kidney injury - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 16:13:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 16:13:55
Data point term sent to Coder	System	01 Dec 2020 16:12:44
User entered 'ACUTE KIDNEY INJURY'	douglas winter (b) (4)	01 Dec 2020 16:12:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '2 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User entered empty.	System	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '3 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User entered empty.	System	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	01 Dec 2020 16:12:31
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	01 Dec 2020 16:12:13
User entered 'No (N)'	douglas winter (b) (4)	01 Dec 2020 16:12:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	01 Dec 2020 16:12:31
User entered '1'	(b) (4)	
	douglas winter (b) (4)	01 Dec 2020 16:12:13
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'ACUTE KIDNEY INJURY WAS A DIAGNOSIS AT HOSPITAL DISCHARGE.'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User entered '0'	System	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14
User entered '0'	System	01 Dec 2020 16:12:13

US3222189

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:14

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as SOC: Psychiatric disorders, HLT: Disturbances in thinking and perception, HLT: Hallucinations (excl sleep-related), PT: Hallucination, visual, LLT: Visual hallucinations - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 16:15:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 16:15:49
Data point term sent to Coder	System	01 Dec 2020 16:14:46
User entered 'VISUAL HALLUCINATIONS'	douglas winter (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '2 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User entered empty.	System	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '3 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User entered empty.	System	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Dec 2020 16:14:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	douglas winter (b) (4)	01 Dec 2020 16:14:33
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 16:14:15
User entered empty.	douglas winter (b) (4)	01 Dec 2020 16:14:15
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'VISUAL HALLUCINATIONS WAS A DISCHARGE DIAGNOSIS.'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User entered '0'	System	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16
User entered '0'	System	01 Dec 2020 16:14:15

US3222189

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:16

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Substance abuse, LLT: Polysubstance abuse - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 16:17:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 16:17:49
Data point term sent to Coder	System	01 Dec 2020 16:16:49
User entered 'POLYSUBSTANCE ABUSE'	douglas winter (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '2 Oct 2020'	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:17:03
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	01 Dec 2020 16:17:03
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 16:16:45
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	01 Dec 2020 16:16:45
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	01 Dec 2020 16:16:45
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:16:45
	(b) (4)	
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 16:16:26
User entered '3 Oct 2020'	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	01 Dec 2020 16:17:03
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	01 Dec 2020 16:17:03
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	01 Dec 2020 16:16:26
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	01 Dec 2020 16:16:26
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'POLYSUBSTANCE ABUSE WAS A DISCHARGE DIAGNOSIS.'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Dec 2020 16:16:26

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
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)	06 Apr 2021 20:12:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:12:43
Data point term sent to Coder	System	06 Apr 2021 20:07:34
User entered 'URINARY TRACT INFECTION'	douglas winter (b) (4)	06 Apr 2021 20:06:36
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '21 Dec 2020'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:06:36
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:06:36
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'I'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:06:36
	(b) (4)	
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 20:06:36
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 20:06:36
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	douglas winter (b) (4)	01 Dec 2020 17:01:07
	(b) (4)	

US3222189

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	douglas winter (b) (4)	06 Apr 2021 20:04:06
DataPoint inactivated with code reason code Data not required.	douglas winter (b) (4)	01 Dec 2020 17:01:07

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User closed query 'Please add all Con Meds from source onto the log. ' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 16:41:58
User closed query 'Per ETRTR: Upon next contact with subject, please confirm no medication has been dosed for SAE "Alcohol Abuse". Update ConMeds and AE CRF otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 16:41:56
User closed query 'Per CDM: "Prior/Concomitant Medication and Vaccination Summary" page is recorded as "Yes" however, Prior/concomitant medications and/or vaccinations page is blank. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 16:08:03
Query 'Please add all Con Meds from source onto the log. ' answered with 'UPDATED' (Site from CRA).	douglas winter (b) (4)	01 Dec 2020 16:49:35
	(b) (4)	
Query 'Per CDM: "Prior/Concomitant Medication and Vaccination Summary" page is recorded as "Yes" however, Prior/concomitant medications and/or vaccinations page is blank. Please review and update accordingly.' answered with 'UPDATED' (Site from DM).	douglas winter (b) (4)	01 Dec 2020 16:49:28
	(b) (4)	
Query 'Per ETRTR: Upon next contact with subject, please confirm no medication has been dosed for SAE "Alcohol Abuse". Update ConMeds and AE CRF otherwise, thanks.' answered with 'PER RECORDS ONLY IV FLUIDS WERE PROVIDED IN ORDER TO CORRECT CREATININE FROM 2 TO 1.2.' (Site from CRA).	douglas winter (b) (4)	01 Dec 2020 16:49:19
	(b) (4)	
User opened query 'Please add all Con Meds from source onto the log. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:46:18
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:44:40
User opened query 'Per CDM: "Prior/Concomitant Medication and Vaccination Summary" page is recorded as "Yes" however, Prior/concomitant medications and/or vaccinations page is blank. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:20:24

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Upon next contact with subject, please confirm no medication has been dosed for SAE "Alcohol Abuse". Update ConMeds and AE CRF otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 23:16:47
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:50:11
User entered 'No (N)'	(b) (4)	
	Amber Vasquez (b) (4)	09 Oct 2020 19:20:17
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 19:56:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:56:28
Data point term sent to Coder	System	04 Nov 2020 19:55:13
User entered 'CALCIUM'	douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'SUPPLEMENT'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:07:46
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 21:46:51
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	23 Dec 2020 13:29:19
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	23 Dec 2020 13:29:05
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 07:52:09
User entered '1'	douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per CDM: Please verify Dose unit should be blank as Dose per administration is recorded as "UNK". Please review and update accordingly. Else clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 12:19:01
Query 'Per CDM: Please verify Dose unit should be blank as Dose per administration is recorded as "UNK". Please review and update accordingly. Else clarify. Thank you' answered with 'corrected ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:07:58
User opened query 'Per CDM: Please verify Dose unit should be blank as Dose per administration is recorded as "UNK". Please review and update accordingly. Else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 02:20:13
User entered 'tablet (TABLET)'	douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UN UNK 2015'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	04 Nov 2020 19:54:28
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 19:54:28

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 20:55:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:55:08
Data point term sent to Coder	System	04 Nov 2020 20:37:29
User entered 'FISH OIL'	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'SUPPLEMENT'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:08:37
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' answered with 'UPDATED ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:22:53
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:22:49
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:01:28
User entered 'UNKNOWN'	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	04 Nov 2020 20:37:12
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:37:12
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UN UNK 2015'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	04 Nov 2020 20:37:12
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:37:12
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	04 Nov 2020 20:37:12
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 20:37:12

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 20:55:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 20:55:26
Data point term sent to Coder	System	04 Nov 2020 20:43:36
User entered 'FOLIC ACID'	douglas winter (b) (4)	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	04 Nov 2020 20:43:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'SUPPLEMENT'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:08:39
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' answered with 'UPDATED ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:23:07
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:23:03
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:01:33
User entered 'UNKNOWN'	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	douglas winter (b) (4)	04 Nov 2020 20:50:06
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	04 Nov 2020 20:43:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:43:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:43:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UN UNK 2015'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 20:43:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 21:10:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:10:36
Data point term sent to Coder	System	04 Nov 2020 20:44:38
User entered 'MULTI-VITAMIN'	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:44:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	04 Nov 2020 20:44:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'SUPPLEMENT'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:44:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:08:41
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' answered with 'UPDATED ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:23:22
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:23:19
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:01:38
User entered 'UNKNOWN'	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:44:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	04 Nov 2020 20:44:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:44:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:44:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:44:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:44:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:44:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'UN UNK 2015'	douglas winter (b) (4)	04 Nov 2020 20:44:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	04 Nov 2020 20:44:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	04 Nov 2020 20:44:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:44:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:44:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:44:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:44:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 20:44:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 20:56:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:56:32
Data point term sent to Coder	System	04 Nov 2020 20:46:41
User entered 'POTASSIUM'	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:46:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:46:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'SUPPLEMENT'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:46:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:08:43
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' answered with 'UPDATED ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:23:35
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:23:32
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:01:47
User entered 'UNKNOWN'	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:46:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	04 Nov 2020 20:46:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:46:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:46:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:46:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:46:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:46:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UN UNK 2015'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:46:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered '0'	douglas winter (b) (4)	04 Nov 2020 20:46:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	04 Nov 2020 20:46:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:46:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:46:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:46:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:46:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 20:46:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 21:10:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:10:38
Data point term sent to Coder	System	04 Nov 2020 20:47:43
User entered 'TURMERIC'	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'SUPPLEMENT'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:08:46
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' answered with 'UPDATED ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:24:26
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:24:13
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:01:52
User entered 'UNKNOWN'	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	douglas winter (b) (4)	04 Nov 2020 20:53:57
	(b) (4)	
User entered 'capsule (CAPSULE)'	douglas winter (b) (4)	04 Nov 2020 20:47:27
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:47:27
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UN UNK 2015'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 20:47:27

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 20:55:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:55:35
Data point term sent to Coder	System	04 Nov 2020 20:48:44
User entered 'VITAMIN D'	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'SUPPLEMENT'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:08:47
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' answered with 'UPDATED ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:24:41
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 15:24:37
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:01:57
User entered 'UNKNOWN'	douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'tablet (TABLET)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
	(b) (4)	
User entered empty.	douglas winter (b) (4)	04 Nov 2020 20:48:35
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UN UNK 2015'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 20:48:35

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: ELECTROLYTES NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 15:26:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 15:26:36
Data point term sent to Coder Coding entries removed.	System douglas winter (b) (4)	06 Apr 2021 20:00:18 06 Apr 2021 19:59:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: ELECTROLYTES NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 22:46:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 22:46:56
Data point term sent to Coder User entered 'IV FLUIDS'	System douglas winter (b) (4)	01 Dec 2020 16:52:41 01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:20:11
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'PLEASE REF TO ACUTE KIDNEY INJURY AE' (Site from DM).	douglas winter (b) (4) (b) (4)	06 Apr 2021 20:00:01
User entered 'AE: ACUTE KIDNEY INJURY: (CREATININE WAS ELEVATED TO A 2 AND FLUIDS DROPPED IT TO A 1.26.)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Apr 2021 19:59:54
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 04:17:38
User entered 'CREATININE WAS ELEVATED TO A 2 AND FLUIDS DROPPED IT TO A 1.26.'	douglas winter (b) (4) (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '1000'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'mL (mL)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '2 Oct 2020'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '2 Oct 2020'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User entered empty.	System	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User entered empty.	System	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:44
User entered empty.	System	01 Dec 2020 16:52:11

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 16:26:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 16:26:47
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	09 Apr 2021 16:26:28 09 Apr 2021 16:25:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 11:28:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 11:28:42
Data point term sent to Coder	System	06 Apr 2021 20:03:25
User closed query 'For coding purposes, please verify the spelling of the medication reported. If spelling is correct, please split to report each medication in different entries and please update the reported term.' (Site from System).	System	06 Apr 2021 20:03:17
Query 'For coding purposes, please verify the spelling of the medication reported. If spelling is correct, please split to report each medication in different entries and please update the reported term.' answered with 'CORRECTED' (Site from System).	douglas winter (b) (4)	06 Apr 2021 20:03:17

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'SULFAMETHOXAZOLE TRIMETHOPRIM' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Apr 2021 20:03:09
User opened query 'For coding purposes, please verify the spelling of the medication reported. If spelling is correct, please split to report each medication in different entries and please update the reported term.' (Site from System).	Coder Import (b) (4) (b) (4)	30 Dec 2020 14:27:31
Data point term sent to Coder	System	30 Dec 2020 14:11:37
User entered 'sulfonate/trimethoprim'	(b) (4), (b) (6) (b) (4)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Per CDM RQ: Thank you for updating the AE page. however please review the indication spelling and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:42:26
Query 'Per CDM RQ: Thank you for updating the AE page. however please review the indication spelling and update accordingly. ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:26:38
User entered 'URINARY TRACT INFECTION' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:25:58
User opened query 'Per CDM RQ: Thank you for updating the AE page. however please review the indication spelling and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 14:18:47
User closed query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 14:18:47
Query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'UPDATED AE PAGE' (Site from DM).	douglas winter (b) (4) (b) (4)	06 Apr 2021 20:03:36
User opened query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 02:40:11
User entered 'urinary track infection'	(b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '800/160'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Dec 2020 14:11:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 14:11:25
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 14:11:16
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User entered '2'	System	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User entered '1'	System	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:49
User entered '804 (804)'	System	30 Dec 2020 14:11:16

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: CEPHALOXIN [CEFALOXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 22:01:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 22:01:23
Data point term sent to Coder	System	06 Apr 2021 20:10:49
User entered 'CEPHALOXIN'	douglas winter (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'AE: URINARY TRACT INFECTION'	(b) (4) douglas winter (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '500'	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'three times daily (TID)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '24 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Apr 2021 20:12:30
User entered '14 Feb 2021'	(b) (4)	
	douglas winter (b) (4)	06 Apr 2021 20:10:01
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '7 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Apr 2021 20:12:30
User entered '21 Feb 2021'	(b) (4)	
	douglas winter (b) (4)	06 Apr 2021 20:10:01
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User entered '3'	System	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User entered '1'	System	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:29:52
User entered '804 (804)'	System	06 Apr 2021 20:10:01

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: OTHER DERMATOLOGICALS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 11:38:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:38:38
Data point term sent to Coder	System	06 Apr 2021 20:21:04
User entered 'UNKNOWN DERMAL FILLER'	douglas winter (b) (4) (b) (4)	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UNKNOW REASON FOR DERMAL FILLER'	(b) (4) douglas winter (b) (4)	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'UNKNOWN'	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'DOSE IS UNKNOWN' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Apr 2021 20:23:23
User entered 'DOSE IS UNKNOW'	(b) (4)	
	douglas winter (b) (4)	06 Apr 2021 20:20:06
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'unknown (UNKNOWN)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) douglas winter (b) (4)	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	06 Apr 2021 20:21:44
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Apr 2021 20:21:34
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:20:06
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '1' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Apr 2021 20:21:44
User entered '0' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Apr 2021 20:21:34
User entered '1'	(b) (4)	
	douglas winter (b) (4)	06 Apr 2021 20:20:06
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Apr 2021 20:21:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Apr 2021 20:20:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	06 Apr 2021 20:20:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 20:20:43
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	06 Apr 2021 20:20:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 20:20:06
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:20:06
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	06 Apr 2021 20:22:29
User entered 'UN UNK 0000' reason for change: Data Entry Error	douglas winter (b) (4)	06 Apr 2021 20:22:29
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	06 Apr 2021 20:21:07
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	06 Apr 2021 20:20:59
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	06 Apr 2021 20:20:43
User entered empty.	douglas winter (b) (4)	06 Apr 2021 20:20:06
	(b) (4)	

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User entered empty.	System	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User entered empty.	System	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:42
User entered empty.	System	06 Apr 2021 20:20:06

US3222189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:04:27

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	01 Dec 2020 16:36:50
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	09 Oct 2020 19:20:06
	(b) (4)	

US3222189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:27

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '2 Oct 2020'	douglas winter (b) (4)	01 Dec 2020 16:37:20
	(b) (4)	

US3222189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'CT OF HEAD'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:37:20

US3222189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:27

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Indication = Adverse Event, please confirm of this was indicated for AE ENCEPHALOPATHY. If yes, please note that the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:48:27
User opened query 'Per DM CLR: Indication = Adverse Event, please confirm of this was indicated for AE ENCEPHALOPATHY. If yes, please note that the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:27:29
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'Adverse Event (AE)'	(b) (4) douglas winter (b) (4) (b) (4)	01 Dec 2020 16:37:20

US3222189

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:27

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered empty.	douglas winter (b) (4)	01 Dec 2020 16:37:20
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:15:34
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered		
'USA-US104-2020-MRNA-1273-P301000007'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:59
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:04
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:06
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	09 Dec 2020 01:06:13
DataPoint Un-verified.	System	09 Dec 2020 01:06:13
User entered 'Yes (Y)'	System	09 Dec 2020 01:06:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:09
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Bruce'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Teresa'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Tracy'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Rankin'	System	17 Mar 2021 17:56:10
User signature succeeded.	System	17 Mar 2021 17:56:10
	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Becker'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Kowalski'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '860 Peachwood Ave'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:12
User entered empty.	System	26 Oct 2020 15:49:35
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Deland'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:15
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered empty.	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:16
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'FL'	douglas winter (b) (4) (b) (4)	23 Oct 2020 22:55:30

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '32720'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:18
User entered empty.	System	26 Oct 2020 15:49:35
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:54:35
User entered 'US'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 15:00:22
User entered '6'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '5'	System	09 Dec 2020 01:06:37
User entered '4'	System	02 Dec 2020 15:43:51
User entered '3'	System	11 Nov 2020 23:48:31
User entered '2'	System	12 Oct 2020 13:06:27
User entered '1'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:15:34
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered		
'USA-US104-2020-MRNA-1273-P301000007'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:59
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:21:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:04
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:06
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	09 Dec 2020 01:06:13
DataPoint Un-verified.	System	09 Dec 2020 01:06:13
User entered 'Yes (Y)'	System	09 Dec 2020 01:06:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:09
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Investigator's First Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Bruce'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Teresa'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Tracy'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Rankin'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Becker'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Kowalski'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '860 Peachwood Ave'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:12
User entered empty.	System	26 Oct 2020 15:49:35
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Deland'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	09 Dec 2020 01:06:29
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:15
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered empty.	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:16
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'FL'	douglas winter (b) (4) (b) (4)	23 Oct 2020 22:55:30

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '32720'	System	17 Mar 2021 17:56:10
User signature succeeded.	System	17 Mar 2021 17:56:10
	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:18
User entered empty.	System	26 Oct 2020 15:49:35
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:54:35
User entered 'US'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 15:00:22
User entered '6'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '5'	System	09 Dec 2020 01:06:37
User entered '4'	System	02 Dec 2020 15:43:51
User entered '3'	System	11 Nov 2020 23:48:31
User entered '2'	System	12 Oct 2020 13:06:27
User entered '1'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:04:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '08/Oct/2020 16:54'	(b) (4) System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:04:27

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.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:06:21
User entered 'I'	(b) (4), (b) (6)	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:15:34
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered		
'USA-US104-2020-MRNA-1273-P301000007'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:59
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:04
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:06
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	09 Dec 2020 01:06:13
DataPoint Un-verified.	System	09 Dec 2020 01:06:13
User entered 'Yes (Y)'	System	09 Dec 2020 01:06:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:09
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Investigator's First Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Bruce'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Teresa'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Tracy'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Rankin'	System	17 Mar 2021 17:56:10
User signature succeeded.	System	17 Mar 2021 17:56:10
	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Becker'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Kowalski'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '860 Peachwood Ave'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:12
User entered empty.	System	26 Oct 2020 15:49:35
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Deland'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:15
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered empty.	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:16
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'FL'	douglas winter (b) (4) (b) (4)	23 Oct 2020 22:55:30

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '32720'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	09 Dec 2020 01:06:29
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:18
User entered empty.	System	26 Oct 2020 15:49:35
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:54:35
User entered 'US'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 15:00:22
User entered '6'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '5'	System	09 Dec 2020 01:06:37
User entered '4'	System	02 Dec 2020 15:43:51
User entered '3'	System	11 Nov 2020 23:48:31
User entered '2'	System	12 Oct 2020 13:06:27
User entered '1'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:04:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '12/Oct/2020 09:06'	(b) (4) System	12 Oct 2020 13:06:27

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:04:27

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.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 13:06:27

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:15:34
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered		
'USA-US104-2020-MRNA-1273-P301000007'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:59
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:04
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:06
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	09 Dec 2020 01:06:13
DataPoint Un-verified.	System	09 Dec 2020 01:06:13
User entered 'Yes (Y)'	System	09 Dec 2020 01:06:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:09
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Bruce'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Teresa'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Tracy'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Rankin'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Becker'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Kowalski'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '860 Peachwood Ave'	System	17 Mar 2021 17:56:10
User signature succeeded.	System	17 Mar 2021 17:56:10
	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:12
User entered empty.	System	26 Oct 2020 15:49:35
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Deland'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:15
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered empty.	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:16
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'FL'	douglas winter (b) (4) (b) (4)	23 Oct 2020 22:55:30

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '32720'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	09 Dec 2020 01:06:29
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:18
User entered empty.	System	26 Oct 2020 15:49:35
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:54:35
User entered 'US'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 15:00:22
User entered '6'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '5'	System	09 Dec 2020 01:06:37
User entered '4'	System	02 Dec 2020 15:43:51
User entered '3'	System	11 Nov 2020 23:48:31
User entered '2'	System	12 Oct 2020 13:06:27
User entered '1'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:04:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '11/Nov/2020 23:48'	(b) (4) System	11 Nov 2020 23:48:31

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:04:27

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.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:43:34
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 23:48:31

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:15:34
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered		
'USA-US104-2020-MRNA-1273-P301000007'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:59
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:21:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:04
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:21:06
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	09 Dec 2020 01:06:13
DataPoint Un-verified.	System	09 Dec 2020 01:06:13
User entered 'Yes (Y)'	System	09 Dec 2020 01:06:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:09
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Bruce'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Teresa'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Tracy'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Rankin'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Becker'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Kowalski'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '860 Peachwood Ave'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:12
User entered empty.	System	26 Oct 2020 15:49:35
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Deland'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:15
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered empty.	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:16
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'FL'	douglas winter (b) (4) (b) (4)	23 Oct 2020 22:55:30

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '32720'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:18
User entered empty.	System	26 Oct 2020 15:49:35
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:54:35
User entered 'US'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 15:00:22
User entered '6'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '5'	System	09 Dec 2020 01:06:37
User entered '4'	System	02 Dec 2020 15:43:51
User entered '3'	System	11 Nov 2020 23:48:31
User entered '2'	System	12 Oct 2020 13:06:27
User entered '1'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:04:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '02/Dec/2020 10:43'	(b) (4) System	02 Dec 2020 15:43:51

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:04:27

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.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 15:43:51

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:15:34
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered		
'USA-US104-2020-MRNA-1273-P301000007'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:59
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:21:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:04
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:06
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	09 Dec 2020 01:06:13
DataPoint Un-verified.	System	09 Dec 2020 01:06:13
User entered 'Yes (Y)'	System	09 Dec 2020 01:06:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:09
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Bruce'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Teresa'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Tracy'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Rankin'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Becker'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Kowalski'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '860 Peachwood Ave'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:12
User entered empty.	System	26 Oct 2020 15:49:35
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Deland'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	09 Dec 2020 01:06:29
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:15
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered empty.	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:16
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'FL'	douglas winter (b) (4) (b) (4)	23 Oct 2020 22:55:30

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '32720'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:18
User entered empty.	System	26 Oct 2020 15:49:35
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:54:35
User entered 'US'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 15:00:22
User entered '6'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '5'	System	09 Dec 2020 01:06:37
User entered '4'	System	02 Dec 2020 15:43:51
User entered '3'	System	11 Nov 2020 23:48:31
User entered '2'	System	12 Oct 2020 13:06:27
User entered '1'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:04:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '08/Dec/2020 20:06'	(b) (4) System	09 Dec 2020 01:06:37

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:04:27

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)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:37

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:15:34
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered		
'USA-US104-2020-MRNA-1273-P301000007'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:59
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:04
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:06
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	09 Dec 2020 01:06:13
DataPoint Un-verified.	System	09 Dec 2020 01:06:13
User entered 'Yes (Y)'	System	09 Dec 2020 01:06:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:09
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Bruce'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Teresa'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Tracy'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Rankin'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Becker'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Kowalski'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '860 Peachwood Ave'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:12
User entered empty.	System	26 Oct 2020 15:49:35
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Deland'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	09 Dec 2020 01:06:29
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:15
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered empty.	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:16
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'FL'	douglas winter (b) (4) (b) (4)	23 Oct 2020 22:55:30

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '32720'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	09 Dec 2020 01:06:29
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:18
User entered empty.	System	26 Oct 2020 15:49:35
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:54:35
User entered 'US'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 15:00:22
User entered '6'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '5'	System	09 Dec 2020 01:06:37
User entered '4'	System	02 Dec 2020 15:43:51
User entered '3'	System	11 Nov 2020 23:48:31
User entered '2'	System	12 Oct 2020 13:06:27
User entered '1'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:04:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
User entered '17/Mar/2021 13:56'	(b) (4) System	17 Mar 2021 17:56:10

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:04:27

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)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:56:10

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:15:34
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered		
'USA-US104-2020-MRNA-1273-P301000007'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:54
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:59
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:21:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Yes (Y)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:04
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:21:06
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	09 Dec 2020 01:06:13
DataPoint Un-verified.	System	09 Dec 2020 01:06:13
User entered 'Yes (Y)'	System	09 Dec 2020 01:06:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:09
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'No (N)'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Investigator's First Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Bruce'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Teresa'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Tracy'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	System	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Rankin'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered 'Becker'	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:55:30
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:55:30
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:53:35
User entered 'Kowalski'	System	08 Oct 2020 16:52:49

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '860 Peachwood Ave'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:12
User entered empty.	System	26 Oct 2020 15:49:35
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	17 Mar 2021 17:56:10
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered 'Deland'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:15
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 01:06:29
User entered empty.	System	09 Dec 2020 01:06:13
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:16
User entered empty.	System	26 Oct 2020 15:49:35
User entered 'FL'	douglas winter (b) (4) (b) (4)	23 Oct 2020 22:55:30

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:00:09
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:25:23
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	17 Mar 2021 17:56:10
User entered '32720'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 01:06:29
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 23:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:18
User entered empty.	System	26 Oct 2020 15:49:35
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:55:30
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:21:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:54:35
User entered 'US'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Mar 2021 15:00:22
User entered '6'	System	17 Mar 2021 17:56:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '5'	System	09 Dec 2020 01:06:37
User entered '4'	System	02 Dec 2020 15:43:51
User entered '3'	System	11 Nov 2020 23:48:31
User entered '2'	System	12 Oct 2020 13:06:27
User entered '1'	System	08 Oct 2020 16:54:24

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:04:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered '29/Mar/2021 11:00'	(b) (4) System	29 Mar 2021 15:00:22

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:04:27

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.	Bruce Rankin (b) (4)	26 Apr 2021 13:55:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 15:00:22

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'USA-US104-2020-MRNA-1273-P301000013'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:50
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Yes (Y)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Yes (Y)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:00
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:04
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:06
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	System	23 Oct 2020 22:43:42
User entered 'Yes (Y)'	System	23 Oct 2020 22:43:42
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Tracy'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Kowalski'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:09
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:12
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:14
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:16
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:23:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'US'	System	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '4'	System	02 Dec 2020 15:44:17
User entered '3'	System	11 Nov 2020 22:35:09
User entered '2'	System	26 Oct 2020 15:49:35
User entered '1'	System	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'USA-US104-2020-MRNA-1273-P301000013'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:50
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Yes (Y)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Yes (Y)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:00
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:04
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:06
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	System	23 Oct 2020 22:43:42
User entered 'Yes (Y)'	System	23 Oct 2020 22:43:42
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Tracy'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Kowalski'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:09
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:12
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:14
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:16
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:23:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'US'	System	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '4'	System	02 Dec 2020 15:44:17
User entered '3'	System	11 Nov 2020 22:35:09
User entered '2'	System	26 Oct 2020 15:49:35
User entered '1'	System	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:04:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '23/Oct/2020 21:41'	(b) (4) System	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:04:27

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.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'USA-US104-2020-MRNA-1273-P301000013'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:50
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Yes (Y)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Yes (Y)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:00
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:04
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:06
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	System	23 Oct 2020 22:43:42
User entered 'Yes (Y)'	System	23 Oct 2020 22:43:42
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Tracy'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Kowalski'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:09
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:12
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:14
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:16
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:23:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'US'	System	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '4'	System	02 Dec 2020 15:44:17
User entered '3'	System	11 Nov 2020 22:35:09
User entered '2'	System	26 Oct 2020 15:49:35
User entered '1'	System	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:04:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '26/Oct/2020 15:49'	(b) (4) System	26 Oct 2020 15:49:35

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:04:27

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.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:34:55
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 15:49:35

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'USA-US104-2020-MRNA-1273-P301000013'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:50
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Yes (Y)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Yes (Y)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:00
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:04
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:06
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	System	23 Oct 2020 22:43:42
User entered 'Yes (Y)'	System	23 Oct 2020 22:43:42
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Tracy'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Kowalski'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:09
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:12
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:14
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:16
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:23:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'US'	System	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '4'	System	02 Dec 2020 15:44:17
User entered '3'	System	11 Nov 2020 22:35:09
User entered '2'	System	26 Oct 2020 15:49:35
User entered '1'	System	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:04:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '11/Nov/2020 22:35'	(b) (4) System	11 Nov 2020 22:35:09

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:04:27

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.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:44:01
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 22:35:09

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'USA-US104-2020-MRNA-1273-P301000013'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:50
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Yes (Y)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:57
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Yes (Y)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:00
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:04
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:06
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	System	23 Oct 2020 22:43:42
User entered 'Yes (Y)'	System	23 Oct 2020 22:43:42
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'No (N)'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Lisa'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered 'Tracy'	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Tracy'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
User entered 'Holloway'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered 'Kowalski'	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
Un-reviewed for Safety.	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:41:51
User entered 'Kowalski'	System	23 Oct 2020 21:41:21

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:09
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'Houston'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:12
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'DELAND'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered 'TX'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:14
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'FL'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:44:01
Un-reviewed for Safety.	System	02 Dec 2020 15:43:51
DataPoint Un-verified.	System	02 Dec 2020 15:43:51
User entered '77081'	System	02 Dec 2020 15:43:51
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 22:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:16
Un-reviewed for Safety.	System	26 Oct 2020 15:49:35
User entered empty.	System	26 Oct 2020 15:49:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered '32720'	douglas winter (b) (4)	23 Oct 2020 22:54:46
	(b) (4)	

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:23:18
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:49:19
User entered 'US'	System	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
	(b) (4)	
User entered '4'	System	02 Dec 2020 15:44:17
User entered '3'	System	11 Nov 2020 22:35:09
User entered '2'	System	26 Oct 2020 15:49:35
User entered '1'	System	23 Oct 2020 21:41:58

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:04:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered '02/Dec/2020 10:44'	(b) (4) System	02 Dec 2020 15:44:17

US3222189

Folder: SAE USA-US104-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:04:27

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.	Bruce Rankin (b) (4)	19 Feb 2021 21:41:56
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:44:17